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# CLINICAL · INVESTIGATION PROGRAM · REPORT



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## DWIGHT DAVID EISENHOWER

ARMY MEDICAL CENTER  
FT. GORDON, GEORGIA 30905

**FY·87**

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19. KEY WORDS (Continue on reverse side if necessary and identify by block number) Unit Summary; Detail Sheet (Study Objective, Technical Approach, Progress, Status); Publications; Presentations.		
20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Subject report identifies the research activities conducted by Dwight David Eisenhower Army Medical Center investigators through protocols approved by the Institutional Review Committee for registration with the Department of Clinical Investigation during Fiscal Year 1986, and other known publications and presentations by the Dwight David Eisenhower Army Medical Center professional staff. A detail sheet of each protocol giving the objective, technical approach, and progress is presented.		

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411

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417

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421

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509

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511

512

513

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## FOREWORD

The cover this year is the first known drawing of a man with syphilis, the great scourge of the early Renaissance. The artist, Albrecht Durer, was a true pioneer of the artistic school which stressed anatomical detail. The print's first appearance in 1496 was less than two years after the famous epidemic outbreak in Naples associated with the French Troops. In 100 hexameters of accompanying text by Theodoricus Ulsenius, the city Physician of Nuremberg, the scourge is attributed to the conjunction of Jupiter and Saturn in 1484. Subsequently, more conventional medical opinion attributed the Morbus Gallicus or French Disease to sailors in Columbus' expedition who were exposed to Haitian natives on Hispaniola.

Although initially attributed to many causes, its venereal relationship was soon recognized. Giovanni di Vigo noted that it developed from "sexual commerce of a healthy man with a sick woman or the contrary." The French called it the "Neapolitan disease" because their soldiers brought it back to France from Naples. In 1530 the poem, "Syphilis Sive Morbus Gallicus," by Girolamo Fracastro popularized the name of the shepherd, Syphilus, as synonymous with the disease. Besides summarizing the known signs and treatment, the poem ended the practice of blaming the disease on other nationalities. Syphilus, meaning susphilein or swineherd, came to bear the stigmatization instead. Interestingly, his study of syphilis led Fracastro to study other epidemics. He published De Contagione a mere 16 years later in a description of typhus. For this early work and his anticipation of germ theory, he is often referred to as the father of epidemiology.

The epidemic nature of the disease led to the closing of previously popular public bath houses. Many of these had been in existence for a millenium, dating from Roman times. This disease was widely regarded then as now as a new disease. It affected people of both high and low social status impartially.

Today, nearly five centuries later, we have a new, fatal sexually transmitted disease which has many parallels to the early forms of syphilis. At the level of human behavior, many of these similarities are intensely intriguing. Public reputations become tarnished. People become fearful that inadequate public measures are being instituted and they panic into irrational behavior.

This theme inspired the English playwright, Edgar, to write and produce "Entertaining Strangers" in an effort to deal with the interpersonal relationships which become complex under these circumstances in real life. He chose a nineteenth century cholera epidemic in southern England to develop his ideas. Its literary intent is to provide contemporary insights into the way real people are affected. He also includes the observation that it is the poor and the dissolute who always bear the brunt of any epidemic.

The impact of the AIDS epidemic is emerging as Army Medical Centers come to grips with various aspects of the disease in people they treat. It has already

ceased being a disease of urban civilian medical centers located in coastal areas. DDEAMC now has one of the largest number of HIV infected patients owing to its large referral area. Research projects are beginning to appear in our annual report. These studies examine various facets of this epidemic in our population. It is no longer limited to the Infectious Disease subspecialty in any exclusive sense. As this democratization of the disease continues, we might be able to paraphrase Sir William Osler's dictum on syphilis by saying that he who knows AIDS, knows medicine.

One of the key reasons for teaching research methodologies to physicians in graduate medical education is to form them in the mental disciplines needed to allow their development as reflective and analytic thinkers about the disordered health problems of their patients. Our program at Eisenhower continues to provide these opportunities with an increasing quality of research in the face of decreasing personnel. The shrinking health care resources has hurt our program in a number of ways. We had the lowest number of people actually available for work this year of any in recent memory. The problem has many etiologies contributing to its net effect.

These problems mirror the larger problems of medicine and biomedical research which face constraints imposed by society. Growth in medical knowledge produces an increased surface area in its interface with the unknown as it expands, raising more questions than it answered. It also produces, by analogy with an expanding sphere, an increase in the volume of applications which now must be supported. It must reach its new dynamic equilibrium with the public's willingness to seek this new knowledge and fund it.

Historically, the various epidemics such as syphilis, cancer, coronary artery disease, and now AIDS have fueled these expansions. Only rarely have true cures been developed. More frequently, the treatment prolongs life at the cost of increased health costs during this prolonged twilight period.

For these reasons, our research must include well-designed management studies aimed at learning the best treatment plans for various subsets of the diseased population. It must evaluate various prognostic indicators in formulating these goals. Such studies help to train our future clinicians in methods for the right use of existing and future knowledge. It is our mission to support these efforts.



KENT M. PLOWMAN  
LTC, MC  
Chief, Department of Clinical Investigation

## UNIT SUMMARY - FISCAL YEAR 1987

### A. Objective.

The Department of Clinical Investigation is responsible to the Deputy Commander for Clinical Services for providing the facilities and atmosphere of inquiry necessary to support and stimulate both basic and clinical medical investigation within DDEAMC.

### B. Technical Approach.

All research, investigational, and training activities within the Department of Clinical Investigation are conducted under the guidance of AR 40-38, AR 40-7, AR 70-25, AR 70-18, and HSC Reg 40-23. Careful monitoring of all approved protocols is conducted in order to assure strict compliance with these applicable regulations.

### C. Staffing.

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
PLOWMAN, Kent M.	LTC	61F00	Chief
DiBenedetto, Margarete	COL		(Attached to Ft Jackson, SC)
Hofmann John R.	MAJ	64F00	Veterinarian
Sutherland, Donald E.	MAJ	68C00	Biochemist
	CPT		Microbiologist
Sherman, Richard A.*	CPT	68T00	Psychobiologist
Decker, Ronald L.	SGT	92B20	NCOIC, Med Lab Sp
Nead, Charles L.	SGT	92B20	Med Lab Sp
Lugo, Jesus**	SGT	92B20	Med Lab Sp
Bilal, Omar A.	SGT	91T10	Animal Sp
McCullers, Manuela	SGT	91T10	Animal Sp
Horner, Jack A.	GM13	01301	Asst C, S. Res Histologist
McPherson, James C. III, PhD	GS12	01320	Biochemist
Prior, Robert***	GS11	00644	Medical Technologist
Martinez, Rosina	GS7	00303	Clinical Protocol Coordinator
Hinton, Alma	GS7	00404	Biological Lab Technician
Zadinsky, James	GS7	01531	Statistics Asst (Temp 1 yr)
Silas, Billy E.†	GS6	00404	Biological Lab Technician
Ferrell, Sandratt	GS4	00312	Clerk Steno
Challenger, Patricia	GS11	00644	Study Coordinator (5-yr term Dermatology Svc, NIH Grant)
Bruno, Glendatt††	GS9	00644	Medical Technician (3-yr term, Dept of Clinical Investigation, VA Grant)

\*PCS Jun 87

\*\*PCS May 87

\*\*\*Transfer Apr 87

† Reassigned Sep 87

†† Transfer Sep 87

††† Grant End Sep 87

D. Funding.

Type	Fiscal Year 86	Fiscal Year 87
Civilian personnel to include benefits	221,608.00	219,828.00
Consumable supplies	74,944.00	77,338.00
Civilian contracts to include consultants	3,939.00	4,212.00
TDY*	6,294.00	10,083.00
Publications	5,229.00	2,909.00
Noninvestment equipment (Minor MEDCASE)		
Other OMA		
OMA Total	19,936.00	314,370.00
MEDCASE	161,350.00	270,198.00
Other	99.00	
Military	379,082.00	394,262.00
Total	872,441.00	978,830.00

\*Includes Clinical Investigation personnel plus other paper presentations from Dwight David Eisenhower Army Medical Center staff and residents.

E. Progress.

Protocol Disposition FY 87

	<u>Completed</u>	<u>Terminated</u>	<u>Ongoing to FY 88</u>
FY 78	-	-	2
FY 79	2	1	-
FY 80	-	-	-
FY 81	3	-	1
FY 82	-	-	-
FY 83	-	-	3
FY 84	-	1	6
FY 85	3	4	3
FY 86	11	3	7
FY 87	11	6	43
	<u>30</u>	<u>15</u>	<u>65</u>

Cont'd from 2-175

→ Table of Contents

TABLE OF CONTENTS

Year Initiated		Page
	Foreword	i
	Unit Summary - Fiscal Year 1987	iii
	Publications	1
	Presentations	9

DEPARTMENT OF CLINICAL INVESTIGATION

1979	Control of Gonadotropin Secretion in the Male Rat. (C)	18
1979	Gastrointestinal Hormones in Non-Ionic Surface Active Agent Induced Delay of Gastric Emptying. (C) (PR) (P)	19
1979	The Experimental Fat Embolism Syndrome: An Electron Microscopic Study of Lung in Three Models. (T)	20
1981	Correlations Between Amount of Information Feedback and Success of Biofeedback Treatments. (C)	21
1981	Investigations of Chronic Phantom Pain. (C) (PR) (P)	22
1981	Experimental Fat Embolism Syndrome: Basic Studies and Evaluation of Currently Available Therapies and New Agents. (C) (PR) (P)	23
1984	A Scanning and Transmission Electron Microscopic Study of the Effects of Cadmium on the Early Developmental Components of the Craniofacial Region of the Hamster Embryo. (O) (PR) (P)	24
1986	Computer Assisted Infrared Imaging in the Diagnosis and Management of Military Basic Training Injuries. (O)	25
1987	Utility of the 60-Kilodalton Oncofetal Tumor Marker in the Effectiveness of Surgical Intervention in the Treatment of Cancer Patients. (O)	26
1987	Red Cell Protection in Major Third Degree Burns in Guinea Pigs. (O)	27

Year  
Initiated

Page

DEPARTMENT OF DENTISTRY )---

1985	Long Term Effectiveness of Sodium Fluoride on Tooth Hypesensitivity with and without Iontophoresis. (C)	28
1986	Ultrastructural Study of Fibroblasts Attachment to Bone Graft Materials: Quantitative Evaluation. (C)	29
1986	Total Intravenous Anesthesia. (C)	30
1986	Determination of Nicotine Levels in the Gingival Crevicular Fluid of Cigarette Smokers with Periodontal Disease. (C)	31
1986	A Dye Leakage Comparison Study Using IRM, High Copper Amalgam Alloy, and Thermoplastic Gutta Percha Retrograde Filling Materials. (C)	32
1986	SEM Evaluation of the Root Surface Following Apical Root Resection Techniques. (C)	33
1987	Diagnosis of Bone Lesions Through Subtraction by Color Additive Radiology. (C)	34
1987	Comparison of Three Surgical Root Planing Approaches to Endotoxin Removal. (O)	35
1987	Identification of Attachment Sites of Human Fibroblasts. (O)	36
1987	The Presence of Nicotine on Roots of Periodontally Diseased Teeth in Smokers. (O)	37
1987	In Vitro Fibroblast Attachment to Fibronectin-Treated Synthetic Implant Materials. (O)	38
1987	Effect of Sodium Fluoride Iontophoresis on Fibroblast Attachment. (T)	39
1987	Comparison of an Experimental Approach to Closed Root Planing with a Conventional Approach. (O)	40
1987	Evaluation of the Apical Seal Produced by Injected Thermoplasticized Gutta-Percha Using a Gutta-Percha Master Cone. (O)	41
1987	Stereomicroscopic Evaluation of Canal Shape Following Hand, Sonic, and Ultrasonic Instrumentation. (O)	42

Year Initiated		Page
1987	Presence of Pneumocystis carinii Organisms in the Oral Cavity and Correlation with the Walter Reed Staging Classification of HIV Positive Patients. (O)	43

#### DEPARTMENT OF FAMILY PRACTICE

1985	The Interrelationship of Exercise and Fitness During Pregnancy and the Postpartum Period. (T)	44
1987	Lower Extremity Stress Fractures: A Demographic Review of Fort Gordon Military Morbidity and an Analysis of the Role of Crutches. (O)	45
1987	Infant Exposure to Tobacco Smoke Pollution: A Trial of Educational Intervention. (O)	46

#### DEPARTMENT OF MEDICINE

1978	Efficacy of Immunotherapy for Systemic Allergic Reaction to Imported Fire Ant Stings. Part I. Human Immunologic Reactivity to Fire Ant Antigens. BB IND 1452 (O) (PR)	47
1983	Use of Isotretinoin in Prevention of Basal Cell Carcinoma. (O)	48
1985	Effect of Ketoconazole Therapy on the Susceptibility of Enteric Fungi to Amphotericin B and Ketoconazole. (T)	50
1985	Extravascular Penetration of Antimicrobial Agents in New Zealand White Rabbits. (C)	51
1986	Comparison of Test for the Diagnosis of Imported Fire Ant (IFA) Allergy. (C) (PR)	52
1987	Causes of Transient Myocardial Ischemia in Asymptomatic and Symptomatic Patients with Coronary Artery Disease. (O)	54
1987	Comparison of Intravenous Abbokinase and Streptokinase in the Treatment of Acute Myocardial Infarction. (O)	55
1987	Evaluation of Dynamic Rate Response Pacing, Incidence of Myocardial Ischemia and Reaction of Epicardial Coronary Arteries. (O)	56
1987	The Detection of Epithelial Dysplasia by Light and Scanning Electron Microscopy in Patients with Barrett's Esophagus. (O)	57

Year Initiated		Page
1987	A Survey of the Sexual Practices of HIV Antibody Seropositive Patients. (O)	58
1987	The Effectiveness of Metoclopramide to Improve Colonic Visibility in Patients Receiving Night Prior Colonic Lavage: A Double Blind Randomized Study. (O)	59
<u>DEPARTMENT OF NURSING</u>		
1984	Transition into Military Nursing: An Evaluation of a Preceptorship Program. (O)	60
1986	The Effects of the Heating and Humidifying of Anesthetic Gases on the Maintenance of Body Temperature: A Replication. (C)	61
1987	The Effects of Preparatory Information on Anxiety Levels Intravenous Catheter Insertion. (C)	62
<u>NUTRITION CARE DIVISION</u>		
1987	Nutrition Education Adherence Trial (NEAT). (O)	63
<u>DEPARTMENT OF PATHOLOGY</u>		
1984	Metastatic Adenocarcinoma of Unknown Primary Site. (O)	64
1986	The Effect of Normal Plasma Dilution Upon the Prothrombin Time and Activated Partial Thromboplastin Time of Heparinized Blood. (C)	65
1987	Pathology Applications of X-ray Spectrometric Micro-analysis. (O)	67
<u>DEPARTMENT OF PEDIATRICS</u>		
1985	Training Laboratory for Neonatal Procedures. (O)	68
1986	Androgen Responsiveness to LHRH Infusion in Adolescent Females with Polycystic Ovarian Syndrome. (O)	69
1986	Androgen Binding and Reductase Activity in Hair Follicles from Hirsute Females. (O)	70

Year Initiated		Page
1986	Neonatal Galactorrhea and Biologically Active Prolactin Levels. (O)	71
1987	Biobehavior and Family Psychodynamics in Precocious and Pseudoprecocious Puberty. (O)	72
<u>DEPARTMENT OF PSYCHIATRY AND NEUROLOGY</u>		
1984	The DDEAMC Alcohol Residential Treatment Facility Outcome Study. (O)	73
1984	Reliability and Agreement of Reports of Children's Symptoms. (O)	74
1985	Family Risk and Protective Factors: A Prospective Study of Obstetric Patients and Their Families. (O)	75
1987	Neuropsychiatric and Psychosocial Aspects of HIV Disease. (O)	76
1987	Job Performance and Job Satisfaction in the Pregnant Soldier: A Comparison of Her Assessment with That of Her Immediate Supervisor. (C)	77
1987	The Home Environment Questionnaire: A Validity Study. (T)	78
1987	Incest: Understanding its Factors on the Military Family. (C)	79
1987	A Correlational Study of the MCMI, the MMPI, and the Physician's Psychiatric Diagnosis. (O)	80
1987	An Evaluation of the Effects of Cognitive Behavioral Training in Enhancing Performance on the Army Physical Fitness Test. (T)	81
1987	The Relationship Between Coping Resources and Utilization of Medical Services by Military Personnel. (O)	82
1987	Child Psychiatric Data Base Project. (O)	83
1987	Maternal Olfactory Recognition of Infants. (O)	84

Year  
Initiated

Page

DEPARTMENT OF RADIOLOGY

1987	The Effect of Oral Hydration on Bone-to-Soft Tissue Ratios and Subject Scan Interpretation in Tc 99m Medronate Bone Scans. (O)	85
------	--	----

DEPARTMENT OF SURGERY

1978	Intraocular Lens Study. (O)	86
1981	Environmental Stress and Electromyographic Correlates of Chronic Posterior Trunk Muscle Pain. (O)	86-a
1983	Assessment of Vertical Banded Gastropasty in Treatment of Morbid Obesity. (O)	87
1983	Microsurgery Skill Lab. (O)	88
1984	Comparison of Thermography and Standard Techniques for Detection, Diagnosis and Tracing of Peripheral Vascular Disease and Disorders Marked by Altered Patterns of Peripheral Blood Flow. (O)	89
1984	Endoscopic Training Lab. (T)	90
1985	Advanced Trauma Life Support Course. (O)	91
1985	The Treatment of Segmental Bone Loss in Rabbit Femora with Alveograf <sup>R</sup> . (T)	92
1985	Implantable Artificial Anal Sphincter (Swine) Phase (II). (C)	93
1986	Ultrasound Evaluation of the Rotator Cuff. (O)	94
1986	Omental Splenic Autotransplantation: Optimal Transplant Size for Maximal Protective Effect Against Pneumococcal Bacteremia. (O) (PR)	95
1986	The Effects of Pentoxifylline (Trental) on Vasculogenic Impotence. (T)	96
1987	A Comparison of Sympathetic Block Versus Placebo Prevention of Post Herpetic Neuralgia. (T)	97

Year Initiated		Page
1987	Postoperative Analgesia After the Addition of Morphine or Hydramorphone to Intrathecal Tetracaine for Total Joint Surgery. (O)	98
1987	Serum Creatine Kinase and the Acute Abdomen. (O)	99
1987	Iontophoresis of Steroids: Does it Affect Rabbit Tendon Strength. (O)	100
1987	Evaluation of the Garren-Edwards Gastric Bubble - A Controlled Clinical Trial. (T)	101
1987	Development of Surgical Techniques in the Simulated Space Environment Using Neutral Buoyancy. (C)	102
1987	Enhancement Video Endoscopy: Preliminary Assessment of Digital Enhancement. (O)	103
1987	A Comparison of Labetalol and Sodium Nitroprusside in Postoperative Patients Undergoing Carotid Endarterectomy. (O)	104
1987	Omental Splenic Autotransplantation: Optimal Transplant Size for Maximal Protective Effect Against Pneumococcal Bacteremia. (O)	105
1987	Evaluation of Plasma Catecholamines in Patients Undergoing General Anesthesia for Surgical Procedures. (O)	106
1987	The Richards II Series Total Hip Prosthesis: A Clinical Review with a Minimum 2-Year Follow-up Evaluation. (O)	107
1987	The Effect of Position and Supplemental Oxygen on Arterial Oxygen Saturation During Transport to the Post-Anesthesia Care Unit. (O)	108
1987	An Evaluation of the Effects of Hearing Protective Devices on Speech Recognition Performance in Noise of Hearing-Impaired Listeners. (O)	109
<u>USA MEDDAC, FORT BENNING, GEORGIA</u>		
1980	Intraocular Lens Study. (O)	110
1985	Adolescent Medicine: Attitudes and Skills of Internal Medicine: Pediatric and Family Practice Residents. (T)	111

Year Initiated		Page
1986	A Phenomenological Study of Patients Receiving Initial Chemotherapy for Carcinoma of the Lung. (T)	112
1986	Efficacy of Postpartum Uterine Exploration and Curretage. (C)	113
1986	Health Risk Appraisal of Early Adolescents. (C)	114
1986	A Randomized, Controlled Trial of Initially Treated Corneal Abrasions: Physician Mandated Every 24 Hours Follow-Up Versus Patient Initiated (PRN) Follow-Up. (O)	115
1986	The Effect of the Internship of Fitness. (O)	116
1987	The Actual Biomechanics of the Parachute Landing Fall and the Proper Conditioning Needed to Minimize Injuries. (C)	117
1987	Visual Reaction Time of Competitive Shooters. (T)	118
1987	A Descriptive Study of the Self-Esteem of Mothers of Father-Daughter Incest Victims. (C)	119
1987	An Exploration of the Relationship Between Client Expectations and the Working Alliance. (O)	120
1987	The Epidemiology of Training Injuries in Army Infantry Trainees. (C)	121
1987	Comparison of Psyllium Plantago and Xanthan Gum in the Dietary Management of Diabetes Mellitus. (O)	122
1987	The Relationship Between Airborne Activities and Knee Pain. (O)	123
1987	Quantifying the Ranger Experience: The Clinical Aspects of Elite Military Training and Over-Training. (O)	124
1987	Core Temperatures in Soldiers During Routine Physical Training. (O)	125
1987	Care Seeking Behavior After a Mass Casualty Episode. (O)	126
<u>USA MEDDAC, FORT CAMPBELL, KENTUCKY</u>		
1981	Intraocular Lens Study. (O)	127

Year Initiated		Page
1987	The Effects of Message Framing on Adaption of Healthy Behaviors in Pregnancy. (C)	128
1987	The Relationship of Health Locus of Control, Health Value and Use of Child Restraint Devices. (C)	129
1987	Accuracy of Skin Temperature Monitoring in Postoperative Patients Using a Liquid Crystal Thermometer. (C)	130
	<u>USA MEDDAC, FORT JACKSON, SOUTH CAROLINA</u>	
1981	Intraocular Lens Study. (O)	131
1986	Gender Role Identity, Self Concept and Successful Mothering. (T)	132
	<u>USA MEDDAC, FORT RUCKER, ALABAMA</u>	
1980	Intraocular Lens Study. (O)	133
	<u>USA MEDDAC, FORT STEWART, GEORGIA</u>	
1984	Intraocular Lens Study. (T)	134
	Author Index	135
	Subject Index	142
	Distribution List	144

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Code:

O - Ongoing  
C - Completed  
W - Withdrawn  
T - Terminated

P - Published  
PR - Presented

PUBLICATIONS FY 87

DEPUTY COMMANDER FOR CLINICAL SERVICES

Manning DT, Xenakis SN: Prevalence of Type A behavior in American combat soldiers and their children. Mil Med (In Press)

DEPARTMENT OF CLINICAL INVESTIGATION

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McNally PR, Herrera J, Englekrk P, Visvesvara GS, Brewer TG: Prospective evaluation of immunofluorescent antibody testing in the diagnosis of giardiasis. Submitted.

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#### DEPARTMENT OF NURSING

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#### DEPARTMENT OF PATHOLOGY

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#### DEPARTMENT OF PEDIATRICS

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Lloyd WC, Leone CR: Avoiding complications in geriatric oculoplastic surgery. Geriatric Ophthalmology. (In Press)

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Goodell TP: Curriculum design: Operational medicine. Submitted Mil Med.

McGlaughlin VC: Lung abscesses in children: Case report and literature review. Submitted J Fam Prac.

Code:

(C) - Results of clinical study

## PRESENTATIONS FY 87

1987 Recipient of the Annual Resident Research Award: MAJ Pushpinder S. Grover, DC, Tingay Dental Clinic, for his paper entitled "Study of Initial Attachment of Fibroblast Cells to Bone Graft Material in vitro." (C)

## DEPT Y COMMANDER FOR CLINICAL SERVICES

Xenakis SN, Marcum JM, Maurer JL, Duffy JC: Consultation in the aftermath of an air tragedy. 140th Annual Meeting Am Psychiatric Assn, Chicago, IL, 14 May 1987.

Jensen PS, Armitage D, Johnson A, Leventhal B, Xenakis SN: Current concepts in management of adolescent disorders. 140th Ann Mtg Am Psychiat Assn, Chicago, IL, 9-15 May 1987.

Jensen PS, Traylor J, Xenakis SN: Parents vs child reports of child symptoms: Whose problem is it? 140th Ann Mtg, Am Psychiat Assn, Chicago, IL, 9-15 May 1987. (C)

## DEPARTMENT OF CLINICAL INVESTIGATION

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Prior RW, McPherson JC III, Kirby SG, Ward DF, McPherson JC Jr: RBC deformability in vitamin D deficient rats. Georgia Nutrition Council Ann Conf, Callaway Gardens, GA, 25-26 Feb 1987. (C)

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Ward DF, Kirby SG, McPherson JC Jr, McPherson JC III: Deformability of normal rat red blood cells. Georgia Academy Sci, Albany, GA, 24-25 Apr 1987. (C)

Matthews PS, Ward DF, Kirby SG, McPherson JC Jr, McPherson JC III: Cholesterol stabilization of red cell membranes. Georgia Academy Sci, Albany, GA, 24-25 Apr 1987. (C)

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#### DEPARTMENT OF DENTISTRY

Hartwell GR: Endo flareups: Their biological basis and management. Third Samuel Seltzer Endo Symposium, Endodontic Alumni Soc, Temple University, Philadelphia, PA, 2-3 Oct 1986.

#### DEPARTMENT OF FAMILY PRACTICE

Little PB: DMSO - wonder drug or hoax. Ann Mtg Am Acad Fam Physicians, San Francisco, CA, 14-18 Sep 1987.

Edwards RJ: Medical attrition from aviation careers. Aerospace Med Assn Mtg, Las Vegas, NV, May 1987.

#### DEPARTMENT OF MEDICINE

Bunker-Soler AL: Comparison of in vivo and in vitro test in the diagnosis of imported fire ant allergy. Assn Mil Allergists, FAMC, Mar 1987. Ann Mtg Am Acad Allergy & Immunology, Washington, DC, Feb 1987. First prize research competition and Dura Pharmaceutical Award for Excellence in Research.

McNally PR, Maydonovitch CL, Wong RKH: The effectiveness of simethicone in improving visibility during colonoscopy: A double blind randomized study. Am Soc Gastrointestinal Endoscopy, Chicago, IL, May 1987.

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Coles E, Faris MR: Pneumatosis cystoides intestinalis: An unusual complication of 5-FU chemotherapy. Army ACP Mtg, San Francisco, CA, Oct 1986.

Guill MA: Borderline tuberculoid leprosy in a Vietnam war veteran. Tri-Service Dermatologic Mtg, Honolulu, HI, May 1987.

#### DEPARTMENT OF PATHOLOGY

Eatherly JB: Mediastinal lymphoblastic lymphoma. Augusta (Georgia) Regional Soc Pathologists, Augusta, GA, 20 Nov 1986.

Eatherly JB: Metastatic signet ring cell carcinoma. Augusta (Georgia) Regional Soc Pathologists, Augusta, GA, 26 Feb 1986.

Nguyen TH: Keratoacanthoma. Augusta (Georgia) Soc Dermatology, Augusta, GA, 21 Sep 1987.

Nguyen TH: Lichenoid dermatitis. Augusta (Georgia) Soc Dermatology, Augusta, GA, 21 Sep 1987.

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Nguyen TH: Mucha-Habermann disease. Georgia Soc Dermatology, Augusta, GA, 21 Sep 1987.

Nguyen TH: Sarcoidosis. Georgia Soc Dermatology, Augusta, GA, 21 Sep 1987.

Thompson SH: Oral manifestations of periodontal pathology. Annual Tri-Service Continuing Education Course in Periodontology, Augusta, GA, 23 Feb 1987.

Watson CV, Townsend GG: A new look at therapeutic drug monitoring. Georgia State Soc Am Med Technologists, Augusta, GA, 18 Oct 1986.

Weir GT: AIDS update. Georgia State Soc Am Med Technologists, Augusta, GA, 18 Oct 1986.

#### DEPARTMENT OF PEDIATRICS

Lutcher CL, Gilman PA, Harris PH: Major abdominal bleeding in patients with hemophilia. Southern Soc Clin Inv, 28-30 Jan 1987.

Gilman PA: Chemotherapy in pregnancy - Risks to fetus and patient. Presented at the Medical Oncology and Hematology Recent Advances, Kiawah Island, SC, 1 Jul 1987.

Gilman PA: Variations on the adult prospective: Hemoglobin values and cancer management in the young. Presented at the Medical Oncology and Hematology Recent Advances, Kiawah Island, SC, 2 Jul 1987.

#### DEPARTMENT OF PSYCHIATRY AND NEUROLOGY

Traylor J, Jensen PS: Stress and depression in children living overseas. Presented Ann Mtg Am Academy Child Psychiatry, San Antonio, TX, 23-27 Oct 1986.

Jensen PS, Armitage D, Johnson A, Levental B, Xenakis SN: Current concepts in management of adolescent disorders. 140th Ann Mtg Am Psychiat Assn, Chicago, IL, 9-15 May 1987.

Jensen PS, Wymes MR: Program characteristics and academic recruitment. 140th Ann Mtg Am Psychiat Assn, Chicago, IL, 9-15 May 1987.

Jensen PS: Informed consent as a treatment strategy. 140th Ann Mtg Am Psychiat Assn, Chicago, IL, 9-15 May 1987.

Jensen PS, Traylor J, Xenakis SN: Parents vs child reports of child symptoms: Whose problem is it? 140th Ann Mtg, Am Psychiat Assn, Chicago, IL, 9-15 May 1987. (C)

Jensen PS, Wymes MR: Resident satisfaction competence and career development. 140th Ann Mtg, Am Psychiat Assn, Chicago, IL, 9-15 May 1987.

Wymes MR, Jensen PS, Zegans L: The "high risk" resident: Demographic characteristics. 140th Ann Mtg, Am Psychiat Assn, Chicago, IL, 9-15 May 1987.

Jensen PS, Wymes MR, Zegans L: Residents at risk vs risky environments. 140th Ann Mtg Am Psychiat Assn, Chicago, IL, 9-15 May 1987.

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#### SOCIAL WORK SERVICE

O'Brien DE: The integration of social work data into an ambulatory care data base. University of Georgia Graduate School Social Work, Athens, GA, Oct 1986.

#### DEPARTMENT OF SURGERY

Brigham RA: Hospital incurred vascular trauma: Management of complications of brachial artery catheterization. Soc Mil Surg, Bethesda, MD, Dec 1986.

Brigham RA: Internal carotid artery occlusion: Risks and benefits of contralateral carotid endarterectomy. S Assn Vascular Surg, Scottsdale, AZ, Jan 1987.

Steely WM: Comparison of partial splenectomy and splenic autotransplant: Protective effect against septic death. Southeastern Surg Congress, Atlanta, GA, Mar 1987. (C)

Opelka FG: Dual radionuclide scintigraphy in the localization of abnormal parathyroid glands. Southeastern Surg Congress, Atlanta, GA, Mar 1987.

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MARTIN ARMY COMMUNITY HOSPITAL  
FORT BENNING, GEORGIA

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Code:

(C) - Results of clinical study.

DETAIL SUMMARY SHEETS

# Detail Summary Sheet

Date: 2 Oct 87 Prot No.: 79-7 Status: Completed  
 Title: Control of Gonadotropin Secretion in the Male Rat.

Start Date: May 79		Est Comp Date:
Principal Investigator(s) James C. McPherson III, PhD		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation		Associate Investigators:
Key Words: Gonadotropins Steroids		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the role of estrogens, progestins and androgens either alone or in combination in the regulation of gonadotropin secretion.

Technical Approach: Immature male and female rats and neonatally androgenized female rats are castrated and given replacement steroid therapy beginning immediately and continuing for five days. These animal models are utilized to study the effects of various steroids both individually and in combination on the control of gonadotropin secretion, including the pituitary sensitivity to LHRH, peptide and neurotransmitter roles. Secondary sex organs are removed and weighed as a measure of biological activity of the steroids. Serum and tissue samples are analyzed for a variety of endocrine components including gonadotropins, peptides, steroids and neurotransmitters.

Progress: No progress has been accomplished on this protocol during FY 87 due to priority of other resident research protocols.

# Detail Summary Sheet

Date: 2 Oct 87 Prot No.: 79-19 Status: Completed  
 Title: Gastrointestinal Hormones in Non-Ionic Surface Active Agent Induced Delay of Gastric Emptying.

Start Date: Jan 80	Est Comp Date:
Principal Investigator(s) James C. McPherson III, PhD, DAC	Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation	Associate Investigators: James C. McPherson, Jr., M.D., Medical College of Georgia
Key Words: Gastric emptying Surfactants Gastric secretion	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: Periodic Review Results

Study Objective: To determine the effect of non-ionic surface active agents on gastric emptying, voluntary food consumption, body weight and blood chemistries.

Technical Approach: Groups of fasted rats were given non-ionic surface active agents followed 30 minutes later by a commercial rat tube feeding diet. Animals were sacrificed at various times after feeding and gastric emptying compared to control groups. In another series of experiments, rats were injected daily for four days with non-ionic surface active agents. Voluntary food consumption before and during treatment was measured. Twenty-four hours following the last injection, the animals were sacrificed and blood drawn for blood chemistries. In an additional series of experiments the effect of non-ionic surface active agents on gastric secretion is being assessed. Cimetidine, a known gastric secretion inhibitor and metoclopramide, a known agent that stimulates motility of the upper gastrointestinal tract without stimulating gastric secretion, have been utilized to access the actions of these non-ionic surface active agents on delayed gastric emptying. Serum gastrin levels were assayed by radioimmunoassay in fed and non-fed rats given saline or Triton WR-1339 (a non-ionic surface active agent which delays gastric emptying).

Progress: No progress has been made on this protocol during FY 87 due to priority of other resident research protocols.

# Detail Summary Sheet

Date: 1 Oct 87      Prot No.: 79-21      Status: Terminated  
 Title: The Experimental Fat Embolism Syndrome: An Electron Microscopic Study of Lung in Three Models.

Start Date: Jun 80	Est Comp Date:
Principal Investigator(s) Jack A. Horner, B.S.	Facility: Eisenhower Army Medical Center
Dept/Svc:	Associate Investigators: James C. McPherson III, PhD James C. McPherson, Jr., M.D., Medical College of Georgia
Clinical Investigation	
Key Words: Fat embolism Electron Microscopy	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:\$1200
	Periodic Review Results

Study Objective: Experimental fat embolism syndrome is usually induced by one of five techniques: 1) fracture of the femur of an animal, 2) injection of extracted or homogenized adipose tissue from a same species donor, 3) injections of olive oil or purified triolein, 4) injection of oleic acid, or 5) injection of mineral oil (all injections given intravenously). In this study the similarity and differences, if any, in these last three techniques (olive oil, oleic acid, and mineral oil) will be investigated.

Technical Approach: Fat embolism is a major (although frequently undiagnosed unless severe) complication in patients with fractures of the long bones and/or severe trauma. The etiological mechanism of this syndrome is still unsettled. The two mechanisms most widely accepted are: 1) fat from the bone marrow of fractured bones or traumatized adipose tissue enter into small broken veins and travel to the lung where blockage of the capillaries and arterioles occur, and 2) after trauma, the circulating lipoproteins in blood coalesce to form globules of fat large enough to block the capillaries of the lung. In addition, once the fat has blocked a capillary or arteriole, the pathogenic events which follow are unclear. The major effect may be a simple blockage, but some investigators believe the most harmful effects result from the release of free fatty acids from the "trapped" fat globules in the lung. This study will attempt to establish the differences which could be important in the clinical syndrome by examining a mineral oil model (pure blockage with no possible release of free fatty acid from the globules), oleic acid (effect of free fatty acid only), and olive oil (fat capable of hydrolysis to yield free fatty acids). This study may add to our basic understanding of the events in the pathogenesis of the clinical fat embolism syndrome and suggest the basis of new methods of treatment.

Progress: The anticipated resumption of this study in FY 87 did not occur due to personnel shortages.

# Detail Summary Sheet

Date: 30 Jul 87      Prot No.: 81-16      Status: Completed  
 Title: Correlations Between Amount of Information Feedback and Success of Biofeedback Treatments.

Start Date: Feb 81		Est Comp Date:
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MSC		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation Psychology Service		Associate Investigators: Anthony Ficara, DDS, COL, DC Roberto Barja, MD, COL, MC Benjamin Hanson, DDS, MAJ, DC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 87 Review Results Continue

Study Objective: To determine whether increasing the amount of information about muscle tension given to patients with muscular control problems will shorten treatment times and increase the overall effectiveness of the treatment.

Technical Approach: For patients with bruxism, half receive muscle tension feedback from the masseter muscle, weekly in the laboratory, and wear a masseter tension monitor nightly at home. The other half does the same with the addition of receiving feedback from the night monitor when they begin tensing their jaws. For patients with subluxation of the patella, muscle tension in the vastus medialis and lateralis will be recorded. Half will receive a combined feedback proportional to their relative tension and half will receive two independent signals juxtaposed in various ways indicating both relative and absolute muscle tension.

Number of subjects enrolled to date: 202  
 Number of subjects enrolled for reporting period: 20

Progress: Project showed that muscle tension biofeedback is effective only when muscle tension is at the correct level for jaw and knee pain.

# Detail Summary Sheet

Date: 1 Oct 87      Prot No.: 81-19      Status: Completed  
 Title: Investigations of Chronic Phantom Pain.

Start Date: Feb 81	Est Comp Date:
Principal Investigator(s) Richard A. Sherman, PhD, CPT, MS	Facility: Eisenhower Army Medical Center
Dept/Svc:	Associate Investigators: Norman Gall, M.D., AMVAH San Antonio
Clinical Investigation	Roberto H. Barja, M.D., COL, MC
Key Words: Phantom pain	Jeff Ernst, PhD, VA, Augusta
Accumulative MEDCASE Cost: \$18,000	Est Accumulative OMA Cost: \$900
	Periodic Mar 87 Review Results Continue

Study Objective: 1) Develop an understanding of the underlying causes of phantom pain; 2) determine the extent of phantom pain among the amputee population; 3) develop comparative differential profiles of amputees with and without phantom pain; and 4) evaluate new treatments of phantom pain.

Technical Approach: All service connected amputees who can be located receive a mail survey requesting information about their amputation, stump pain, phantom pain, etc. All service connected veterans living near DDEAMC and all amputees treated at DDEAMC or VAMC Augusta are asked to participate in a psychometric and psychophysiologic profile. All phantom pain patients seen at any participating center receive the same profile as part of the pretreatment workup.

Number of subjects enrolled to date: 212

Number of subjects enrolled this reporting period: 93

Progress: Project showed that there are physiological bases for burning and cramping phantom pain. It also showed that phantom limb pain makes a significant impact on the lives of the majority of amputees.

# Detail Summary Sheet

Date: 2 Oct 87      Prot No.: 81-42      Status: Completed  
 Title: Experimental Fat Embolism Syndrome: Basic Studies and Evaluation of  
 Currently Available Therapies and New Agents.

Start Date: Oct 81	Est Comp Date:
Principal Investigator(s) James C. McPherson III, PhD	Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation	Associate Investigators: Jack A. Horner Robert Prior
Key Words: Fat embolism      Red blood cells Surfactants	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: Evaluation of current therapies and new therapies for treatment of fat embolism syndrome in an experimental animal model.

Technical Approach: This project is being investigated in five phases. Metabolic evaluation of the non-ionic surface active agents is being conducted using an eleven parameter profile developed to screen these agents and analyzed by a Technicon RA-1000 (a mini-SMA instrument). The profile includes cholesterol, triglyceride, glucose, urea N, creatinine, uric acid, bilirubin, LDH, SGOT, CPK and ALT. Blood cell indices including mechanical and osmotic fragility and elasticity of the red blood cell membrane are under investigation.

## Progress:

1. Red blood cells from hypervitaminosis D rats have decreased mechanical fragility and decreased deformability indicating an altered red cell membrane.
2. Surfactant F-68, a drug we have previously shown to be effective in the treatment of fat embolism shows a decreased mechanical fragility and decreased deformability, indicating an altered red cell membrane.
3. Cholesterol appears to stabilize the red cell membrane against mechanical stress.
4. There is a progression of decreased deformability of red blood cells from weaning thru aged rats.

# Detail Summary Sheet

Date: 7 Oct 87		Prot No.: 84-50		Status: Ongoing	
Title: A Scanning and Transmission Electron Microscopic Study of the Effects of Cadmium on the Early Developmental Components of the Craniofacial Region of the Hamster Embryo					
Start Date: Jul 84			Est Comp Date:		
Principal Investigator(s) Jack A. Horner, B.S. Thomas F. Gale, PhD			Facility: Eisenhower Army Medical Center Medical College of Georgia		
Dept/Svc: Clinical Investigation Anatomy Dept, MCG			Associate Investigators:		
Key Words: Electron microscopy, Cadmium, Teratology					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Sep 87 Review Results Continue	

Study Objective: To utilize electron microscopy to compare the fine structural features of the component tissues of 13 different regions of the face at selected timed-intervals during the early development of the craniofacial region in cadmium-exposed vs control hamster embryos.

Technial Approach: Cadmium sulfate solution is injected (IV) into timed pregnant golden hamsters on the eighth gestation day (8 AM) and embryos are collected at selected times during the period of early facial development, i.e., day 8 at 6PM; day 9 at 8AM; day 10 at 8 AM; day 10 at 6PM; day 11 at 8 AM. The embryos are fixed, dehydrated by critical point drying, coated with gold, and examined and photographed in the scanning electron microscope. Comparisons between embryos from the control (sham-injected) and experimental (cadmium-injected) pregnant hamsters will reveal the teratogenic effects of cadmium on the developing embryonic face. The comparisons will be both qualitative and quantitative. Collection of the quantitative data on surface area measurements will be accomplished by utilization of a computer interfaced morphometric digitometer system.

Progress: A revised manuscript, submitted for publication in FY 86, has been accepted for publication in the fall of 1987. This reports the results pertaining to surface area measurements for the frontal view of the gestation day 10-8AM embryos. Work has begun on the transmission electron microscopic examination and x-ray energy analysis localization of the cadmium in the developing embryo. Preliminary work has begun on a correlation of these results with a morphological, embryo, staging system based on equivalent somite numbers and crown rump lengths in order to determine whether the detrimental effects of cadmium are site specific or due to growth retardation.

# Detail Summary Sheet

Date: 1 Oct 87		Prot No.: 86-28		Status: Ongoing	
Title: Computer Assisted Infrared Imaging in the Diagnosis and Management of Military Basic Training Injuries.					
Start Date: May 87			Est Comp Date: Nov 87		
Principal Investigator(s) Margarete DiBenedetto, MD, COL MC			Facility: USAMEDDAC, Ft Jackson, SC		
Dept/Svc: Physical Medicine			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine possible utilization of thermography in the diagnosis and treatment of injuries received during military basic training.

Technical Approach: Basic trainees were imaged with infrared scanning before training and every two weeks thereafter. Six positions were utilized to thermographically examine the lower extremities.

Number of subjects enrolled to date: 100

Progress: Data collection completed. Presently 3000 thermograms are being analyzed by two independent investigators. Preparation of several scientific papers is planned. Findings seem to suggest considerable usefulness of this technique in the evaluation of injuries incurred in military basic training. Results and discussions will be submitted as soon as available

# Detail Summary Sheet

Date: 1 Oct 87	Prot No.: 87-16	Status: Ongoing
Title: Utility of the 60-Kilodalton Oncofetal Tumor Marker in the Effectiveness of Surgical Intervention in the Treatment of Cancer Patients.		
Start Date:	Est Comp Date:	
Principal Investigator(s) Donald E. Sutherland, MAJ, MS	Facility: Eisenhower Army Medical Center	
Dept/Svc: Clinical Investigation, Surgery	Associate Investigators: Roosevelt J. Stallings, MD, MAJ, MC	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine if the 60-kilodalton tumor marker is effective in monitoring the tumor status of patients with various types of cancer by determination of its activity post-surgery.

Technical Approach: (1) Patients undergoing surgery for colon, breast, and lung cancer, and melanoma will have plasma drawn prior to surgery and 48 and 72 hours after surgery. The 60-kilodalton oncofetal tumor marker will be determined in all specimens and compared with results obtained in healthy volunteers. If possible, cancer patients will have plasma drawn and assays run on followup examinations, three to six months after surgery.

(2) Manpower consists of one research biochemist and one enlisted technician. This is sufficient to perform the required assays.

(3) This protocol has been allocated \$5875, of which approximately \$1000 has been spent on consumable supplies and animals, all in FY 87.

Total number of subjects enrolled to date: 12

Progress: Plasma has been collected from eight surgical patients and four healthy volunteers to be used in the development of the assay procedure. Due to the technical intensity of the assay procedure and the differences in equipment between DDEAMC and the Ohio State University, where the assay was developed, a workable assay procedure has not yet been developed. Experiments have been designed to determine the cause of the problem, but have not yet been carried out.

# Detail Summary Sheet

Date: 2 Oct 87 Prot No.: 87-17 Status: Ongoing  
 Title: Red Cell Protection in Major Third Degree Burns in Guinea Pigs.

Start Date: Feb 88	Est Comp Date: Feb 89
Principal Investigator(s) Paul W. Paustian, MD, CPT, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation	Associate Investigators: James C. McPherson III, PhD Roosevelt Stallings, MD, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To analyze in an animal model the protective effect of surfactants in preventing hemolysis and erythrocyte cell membrane damage following exposure of the subject to a 50-80% burn surface area. To correlate any beneficial effect with an optimum plasma concentration of the surfactant.

Technical Approach: The established method of Adams et al (Circ Shock 1981; 8:613) will be used. Serial blood samples will be drawn 1 hour post burn and at six hour intervals through 36 hours and analyzed for hematocrit, hemolysis, red blood cell fragility and elasticity. Six groups of animals will represent: 1) control - sham, 2) control - without blood drawn, 3) surfactant IV, 30 min post burn, 4) surfactant IV, 60 min post burn, 5) surfactant IV 90 min post burn, and 6) surfactant IV immediately prior to burn.

Progress: No progress has been made on this protocol due to the temporary reassignment of the resident.

# Detail Summary Sheet

Date: 9 Jul 87		Prot No.: 85-16		Status: Completed	
Title: Long Term Effectiveness of Sodium Fluoride on Tooth Hypersensitivity With and Without Iontophoresis.					
Start Date: Apr 85			Est Comp Date: Jun 87		
Principal Investigator(s) David Kern, MAJ, DC			Facility: Dental Activity		
Dept/Svc: Dentistry/Periodontics			Associate Investigators: Michael McQuade, COL, DC		
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Mar 87 Review Results Continue	
Study Objective: To enhance the effectiveness of current treatment modalities for hypersensitive teeth.					

Technical Approach: The iontophoresor will be connected to the teeth in both treatment groups, but will be activated in only one. This procedure will help to blind the patient to the procedure. Mechanical and thermal stimulation will be used to quantitate a patient response and assess the efficacy of the treatment modalities.

Number of subjects enrolled to date: 20

No adverse reactions.

Progress: Statistical treatment of data consisted of multi-variate analysis of variance. There was no statistically significant advantage demonstrated by iontophoresis with the 2% sodium fluoride over the topical application of 2% sodium fluoride alone. No significance was found when comparisons were made for treatment effects, time effects, or effects of treatment over time. Clinically significant trends were discovered, however, which did tend to show an advantage for iontophoresis. Using pressure as a testing parameter, immediately post-treatment 75% of experimental teeth improved over control. This trend was maintained over time, where at six month evaluation 76% of experimental teeth were improved over their control. Using the air blast as a test blast immediately post-treatment 86% of the experimental teeth did better than their matched control. At the six month re-evaluation, only 61% remained improved over control. Results demonstrate that mechanical stimulation with a pressure sensitive probe is highly reliable. The one second air blast was also reliable though at a lower level of confidence.

# Detail Summary Sheet

Date: 22 Jul 87		Prot No.: 86-9		Status: Completed	
Title: Ultrastructural Study of Fibroblasts Attachment to Bone Graft					
Materials: Quantitative Evaluation					
Start Date: Feb 86			Est Comp Date:		
Principal Investigator(s)			Facility:		
Pushpinder S. Grover, MAJ, DC			Tingay Dental Clinic		
Dept/Svc:			Associate Investigators:		
Dentistry, Clinical Investigation			James C. McPherson III, PhD		
Key Words:			Jack A. Horner		
			Michael McQuade, COL, DC		
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To investigate, in vitro, the nature of the attachment and the relationship between most commonly used intra-osseous implant materials and surrounding connective tissue. Also to quantitate the elements of adhesion.

Technical Approach: Fibroblast cells obtained from commercial sources will be made to grow on most commonly used bone graft materials namely Interpore, Synthograft, Calcitite and Freeze Dried Bone in vitro to study the attachment elements.

Progress: Coverslips of Genitube were prepared with a uniform surface layer of Calcitite, Synthograft, Interpore and demineralized freeze dried bone allograft (FDBA). Suspensions of human foreskin fibroblasts containing approximately 150,000 cells were placed on the coverslips in the Genitube and incubated at 37°C. Uncoated glass coverslips served as controls. At 0,15, 30,45,60,90,120,180 and 240 minutes after inoculation, three Genitubes from each group were shaken at 100 rpm for one minute to remove unattached cells. Coverslips were then processed for light and electron microscopic examination. Results showed that there was a gradual increase in the number of attached cells over the four hour period. On a per weight basis Synthograft permitted more attachment than Calcitite or Interpore, while FDBA showed significantly less attachment than the other three materials ( $p < .001$ ). However, when the number of cells per unit of surface area were calculated, Calcitite had more cells attached than Synthograft or Interpore ( $p < .001$ ). The ability of the cells to adhere may be a function of the porosity of the material and its surface charge distribution. The bone graft material of most osteogenic potential has been found to have the least number of fibroblasts. It is, therefore, extrapolated that the early fibroblast attachment may induce osteogenesis and less fibrous capsule formation. Thus, Calcitite and Synthograft may be less desirable bone graft material than Interpore and FDBA.

# Detail Summary Sheet

Date: 22 Jul 87      Prot No.: 86-12      Status: Completed  
 Title: Total Intravenous Anesthesia.

Start Date: Jul 86	Est Comp Date: May 87
Principal Investigator(s) Henry S. Plautz, LTC, DC	Facility: Eisenhower Army Medical Center
Dept/Svc: Dentistry/Anesthesia	Associate Investigators: G. Lee Brookshire, MD, MAJ, MC Edson O. Parker, MD USA Valley Medical Center Las Vegas, Nevada
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To assess the effects of a total intravenous anesthesia technique (TIVA) using only a narcotic, barbiturate and oxygen or compressed air. The TIVA technique will be compared to the routine standard inhalational anesthetic technique.

Technical Approach: The approach is well standardized for both the intravenous and inhalation techniques.

Number of subjects enrolled to date: 65  
 Number of subjects enrolled for reporting period: 23

Progress: In this study the delivery of anesthesia via the TIVA technique compares favorably with the balanced technique in oral surgery outpatient procedures. TIVA may have application in a variety of clinical situations. In areas of limited logistical support such as in third world countries, or on the battlefield it may be employed where the lack of anesthesia gases or machines may handicap anesthesia delivery. The TIVA technique also affords a totally disposable method of anesthetic delivery consistent with the current philosophy in the management of patients suffering from contagious pulmonary infections or AIDS.

# Detail Summary Sheet

Date: 22 Jul 87	Prot No.: 86-14	Status: Completed
Title: Determination of Nicotine Levels in the Gingival Crevicular Fluid of Cigarette Smokers with Periodontal Disease.		
Start Date: Mar 86	Est Comp Date: Jul 87	
Principal Investigator(s) James R. McGuire, MAJ, DC	Facility: Tingay Dental Clinic	
Dept/Svc: Dentistry, Clinical Investigation	Associate Investigators: Michael McQuade, COL, DC Anthony Ficara, COL, DC	
Key Words: Nicotine, Crevicular fluid		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
Study Objective: To determine if nicotine resides in the gingival crevicular fluid of smokers with periodontal disease, and if so, at what concentration.		

Technique Approach: Sample collection technique was modified to use filter papers instead of micropipettes. Five Periotron filter papers are separately inserted into the gingival sulcus of periodontal patients at Tingay Dental Clinic as part of the examination process. Fluid is absorbed onto the papers over a 60-second period, the papers are removed, weighed, and analyzed for nicotine and its metabolite cotinine using High Performance Liquid Chromatography at Clinical Investigation Lab. Saliva samples are also taken.

Number of subjects enrolled to date: 35

Number of subjects enrolled during reporting period: 28

Progress: All of the 13 non-smokers contained less than 0.15 ng/mL (level of detection) cotinine in both saliva and gingival crevicular fluid samples. In the samples taken from 22 smokers, the mean saliva cotinine concentration was  $420 \pm 150$  ng/mL (range 157 - 1054 ng/mL). The mean crevicular fluid cotinine concentration was  $2600 \pm 2195$  ng/g (range 0 - 15,098 ng/g). The extraction procedure yielded a 57.7% extraction efficiency. The results demonstrated a highly significant difference between both saliva and crevicular fluid cotinine levels in smokers vs non-smokers ( $p < 0.000+$ ). Regression analysis demonstrated very weak correlations between saliva and crevicular fluid cotinine levels and the time elapsed since the last cigarette (0.010 and -0.183, respectively). No regression analysis was run using daily cigarette consumption since the majority of the patients sampled smoked similar amounts.

# Detail Summary Sheet

Date: 22 Jul 87	Prot No.: 86-21	Status: Completed
Title: A Dye Leakage Comparison Study Using IRM, High Copper Amalgam Alloy, and Thermoplastic Gutta Percha Retrograde Filling Materials.		
Start Date: May 86	Est Comp Date:	
Principal Investigator(s) Daniel L. Bondra, DDS, MAJ, DC	Facility: Tingay Dental Clinic	
Dept/Svc: Dentistry/Endodontics	Associate Investigators: Frank Portell, DDS, LTC, DC Gary Hartwell, DDS, COL, DC	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate and compare the seal created by IRM, thermoplastic gutta percha, and high copper amalgam alloy following apical root resection. This study will be conducted in vitro using single rooted teeth which have already been extracted as a result of severe caries or other clinical conditions rendering them non-restorable.

Technical Approach: All obturated experimental teeth will be stored in saline for 14 days at 37°C, then two coats of sticky wax and nail polish will be applied to the crown and root surfaces except for the area of the apical foramen. The apical one-half of all roots will be emerged in 2% methylene blue dye for 48 hours. After exposure to the dye, the teeth will be removed and dried. The sticky wax and nail polish will be removed and the tooth structure cleared. The specimens will be decalcified, then dehydrated in a series of ethyl alcohol rinses. The dehydrated teeth will then be placed in methyl salicylate to make them transparent. Penetration of methylene blue dye into the canal system will then be measure linearly using a 50 X stereolight microscope.

Progress: An in vitro dye leakage study was performed to compare the sealing ability of amalgam with copalite, IRM, and EBA cement when used as retro-filling materials. Forty-five freshly extracted anterior teeth were obturated with gutta-percha, the apical 3mm of the roots were resected and 2mm deep retrograde preparations were performed. The roots were then randomly placed into three groups and retrofilled with one of the experimental materials. Following 72 hours in India ink, the teeth were cleared and evaluated for leakage using a stereomicroscope. Statistical analysis of the results showed that IRM and EBA cement samples had significantly less leakage than amalgam with copalite. No statistically significant difference was found between the EBA cement and IRM samples.

# Detail Summary Sheet

Date: 22 Jul 87		Prot No.: 86-22		Status: Completed	
Title: SEM Evaluation of the Root Surface Following Apical Root Resection Techniques.					
Start Date: May 86			Est Comp Date:		
Principal Investigator(s)			Facility:		
Theodore A. Nedderman, DDS, MAJ, DC			Tingay Dental Clinic		
Dept/Svc:			Associate Investigators:		
Dentistry, Clinical Investigation			Gary Hartwell, DDS, COL, DC		
Key Words:			Jack A. Horner		
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To qualitatively and quantitatively evaluate the root surface following apical root resection with three different burs in both high speed and low speed air rotor handpieces.

Technical Approach: The study will be conducted in vitro using the palatal roots of human maxillary molar teeth which previously extracted due to caries or other clinical conditions which rendered them non-restorable.

Progress: A scanning electron microscope was used to evaluate the surface properties of the cut root end and gutta-percha obturating material following apical root resection. The palatal roots of 35 extracted human maxillary molars were instrumented and obturated with laterally condensed gutta-percha and Roth 801 sealer. Thirty roots were divided into six equal groups and apical root resections were formed using three bur configurations in both high speed and low speed handpieces. Five roots were resected with a slow speed diamond saw and served as controls. Different surface characteristics were produced using the same bur configuration with the high speed and low speed handpieces. The smoothest surface and the least amount of gutta-percha disturbance was produced by the #57 plain fissure bur in the low speed handpiece. The roughest and most irregular surfaces were produced by the crosscut fissure burs in both high and low speed resections. Both the crosscut and plain fissure burs tended to shred and tear the gutta-percha when used with the high speed handpiece.

# Detail Summary Sheet

Date: 13 Aug 87	Prot No.: 87-4	Status: Completed
Title: Diagnosis of Bone Lesions Through Subtraction by Color Additive Radiology.		
Start Date:	Est Comp Date:	
Principal Investigator(s) Randolph Masuda, CPT, DC	Facility: Tingay Dental Clinic	
Dept/Svc: Dental Activity	Associate Investigators: Michael J. Scheidt, COL, DC	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To compare subtraction by color addition rather than digital subtraction images to conventional radiographic images to determine if diagnostic performance is affected.

Technical Approach: A subtraction by color addition viewbox measuring 12 inches long by 6 inches wide and 8 inches high was fabricated to allow viewing of the image. Custom intraoral radiographic stents were fabricated for three human skulls. Preoperatively, radiographs of all sites under study were made using double film packets. Osseous defects were then prepared on facial and interproximal surfaces with a number 6 round bur. Pre and postoperative radiograph pairs were mounted in the subtraction by color addition viewbox and photographed with 35 mm color slide film. This constituted the experimental group. Control group I consisted of slides of the image produced from two identical postoperative radiographs mounted in the viewbox. Control II were slides of conventionally mounted postoperative radiographs.

Progress: Comparison of the conventional interpretation of postoperative radiographs, Control group II, with the interpretation of postoperative radiographs using the addition of colored filters, Control group I, revealed no significant differences between scores for true positive, false positive and false negative values. Comparison of the experimental group, interpretation of radiographs using subtraction by color addition, with Control group I and with Control group II showed significant differences at the .05 level. Comparison of false positive values revealed no significant differences between any of the groups.

# Detail Summary Sheet

Date: 8 Oct 87		Prot No.: 87-18		Status: Ongoing	
Title: Comparison of Three Surgical Root Planing Approaches to Endotoxin Removal.					
Start Date: Jan 87			Est Comp Date: Jun 88		
Principal Investigator(s) Mary H. Burke, MAJ, DC			Facility: Tingay Dental Clinic, DDEAMC		
Dept/Svc: Dental Activity			Associate Investigators: Jeffrey Rossman, COL, MC		
Key Words: Root planing; Endotoxin removal			Michael J. Scheidt, COL, MC		
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To evaluate and compare the quantity of bacterial endotoxin remaining on root surfaces following three instrumentation procedures: root planing with Gracey curettes; use of a Cavitron ultrasonic scaler; and use of an air-powder abrasive system, the Prophy Jet.

Technical Approach: Teeth extracted for periodontic reasons on emergency service collected for study. Manpower to include myself and Dr. McPherson.

Progress: To date 30 teeth have been collected for study and Limulus Lysate Assay Kit has arrived. Teeth are sectioned (5) to run test batch to calibrate assay. All teeth are being sectioned longitudinally with one side treated, other side pilot. Initial 5 teeth are ready for assay to calibrate and determine effect of toothbrushing on root surface.

# Detail Summary Sheet

Date: 8 Oct 87 Prot No.: 87-19 Status: Ongoing  
 Title: Identification of Attachment Sites of Human Fibroblasts.

Start Date:	Est Comp Date:
Principal Investigator(s) Richard L. Emert, MAJ, DC	Facility: Tingay Dental Clinic, DDEAMC
Dept/Svc: Dental Activity/Clinical Investigation	Associate Investigators: James C. McPherson III, PhD Jack A. Horner Michael J. McQuade, COL, DC Michael J. Schiedt, COL, DC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To study the mechanism of attachment of fibroblasts and "map" fibroblast sites of attachment using electron microscopy and x-ray energy spectroscopy analysis.

Technical Approach: Incubate cultured fibroblasts (human gingival) at various times. At these various times (0-300 minutes), add sulfnydryl binding reagents (both standard and fluorescent) to fibroblasts. Sulfnydryl binding reagent will supposedly bind the proteins at the attachment sites. Then, map the sites using SEM, x-ray spectroscopy, and fluorescence.

Progress: Ongoing, no reportable data available yet.

# Detail Summary Sheet

Date: 8 Oct 87	Prot No.: 87-20	Status: Ongoing
Title: The Presence of Nicotine on Roots of Periodontally Diseased Teeth in Smokers.		
Start Date: Jul 86	Est Comp Date: Jun 88	
Principal Investigator(s) Murray J.A. Cuff, CPT, DC	Facility: Tingay Dental Clinic, DDEAMC	
Dept/Svc: Dental Activity/Clinical Investigation	Associate Investigators: Michael J. McQuade, COL, DC Michael J. Scheidt, COL, DC Donald Sutherland, MAJ, MS	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the presence of nicotine on the roots of periodontally diseased teeth in smokers at the supragingival, periodontal pocket and attached root levels.

Technical Approach: Extract nicotine from 15-20 previously extracted periodontally diseased smokers' teeth. Quantitative analysis will be performed and reported as mass of nicotine per mass (or surface area) of tooth root at the supragingival, periodontal pocket and attached levels.

Progress: A variety of extraction techniques have been attempted for use with both the high pressure liquid chromatograph (HPLC) and gas chromatograph (GC) with inconsistent results on both smokers and non-smokers teeth. A recent, simplified extraction technique for HPLC is giving promising results on test teeth. Sample teeth have been collected and stored.

# Detail Summary Sheet

Date: 8 Oct 87		Prot No.: 87-21		Status: Ongoing	
Title: In Vitro Fibroblast Attachment to Fibronectin-Treated Synthetic Implant Materials.					
Start Date: Feb 87			Est Comp Date: May 88		
Principal Investigator(s) Steven C. Guy, MAJ, DC			Facility: Tingay Dental Clinic, DDEAMC		
Dept/Svc: Dental Activity/Clinical Investigation			Associate Investigators: Jeffrey A. Rossman, COL, DC Michael J. McQuade, COL, DC James C. McPherson III, PhD		
Key Words: Fibronectin, Implant, Hydroxylapatite, Fibroblast, Titanium					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine if fibronectin increases the attachment of fibroblasts to synthetic implant material (hydroxylapatite and tricalcium phosphate).

Technical Approach: Fibroblast attachment and adhesion to titanium, porous hydroxylapatite, and non-porous hydroxylapatite will be quantified using radioactively tagged gingival fibroblasts. Attachment and adhesion will be measured using fibronectin-treated implant materials and non-treated implant materials.

Progress: Literature search has been completed. All of the test materials have been purchased and prepared for use. MCG is in the process of growing radioactively tagged fibroblasts for use in the experiment. Experimental design was finalized following meetings with the DDEAMC statistician and Dr. Van Dyke of Emory University. I plan to run the experiment within the next 4-6 weeks and prepare the results for publication shortly thereafter.

# Detail Summary Sheet

Date: 8 Oct 87      Prot No.: 87-22      Status: Terminated  
 Title: Effect of Sodium Fluoride Iontophoresis on Fibroblast Attachment.

Start Date: Jan 87		Est Comp Date: Apr 88
Principal Investigator(s) James N. Hamilton, MAJ, DC		Facility: Tingay Dental Clinic, DDEAMC
Dept/Svc: Dental Activity		Associate Investigators: Michael J. Scheidt, COL, DC
Key Words:		Jeffrey A. Rossman, COL, DC
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine, in vitro, if iontophoresis used to apply sodium fluoride results in any decrease in fibroblast attachment to a root surface.

Technical Approach:

Progress: Study not implemented, terminate.

# Detail Summary Sheet

Date: 8 Oct 87		Prot No.: 87-23		Status: Ongoing	
Title: Comparison of an Experimental Approach to Closed Root Planing With a Conventional Approach.					
Start Date: Jan 87			Est Comp Date: Jun 88		
Principal Investigator(s) Emanuel J. Hnarakis, MAJ, DC			Facility: Tingay Dental Clinic, DDEAMC		
Dept/Svc: Dental Activity			Associate Investigators: Jeffrey A. Rossman, COL, DC Michael J. McQuade, COL, DC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To evaluate two combinations of instrumenting proximal root surfaces for efficiency in plaque and calculus removal and attempt to correlate problems with removal of plaque and calculus with access. Also to examine a representative sample of the instrumented surfaces under SEM for desirable and undesirable characteristics of instrumented root surfaces.

Technical Approach: Clean contralateral pairs of teeth in vivo. Extract and analyse root surface with stereomicroscope, photos and computer with digitizing tablet (to calculate areas).

Number of subjects enrolled to date: 18

Progress: Have collected 18 paired samples; have analysed half of these via stereomicroscope and computer. So far neither method appears to have a clear superiority. Still collecting pairs of teeth.

# Detail Summary Sheet

Date: 6 Oct 87	Prot No.: 87-32	Status: Ongoing
Title: Evaluation of the Apical Seal Produced by Injected Thermoplasticized Gutta-Percha Using a Gutta-Percha Master Cone.		
Start Date: Mar 87	Est Comp Date:	
Principal Investigator(s) Arvid K. Olson, LTC, DC	Facility: Tingay Dental Clinic, DDEAMC	
Dept/Svc: Dental Activity	Associate Investigators: R. Norman Weller, COL, DC Gary R. Hartwell, COL, DC	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Study is designed to qualitatively and quantitatively evaluate the obturation and apical seal obtained using a master gutta-percha cone and back-filling the canal with injected thermoplasticized gutta-percha. The study will be conducted in vitro using the roots of human teeth which were previously extracted due to caries of other clinical conditions which rendered them non-restorable.

Technical Approach: An evaluation of the apical seal obtained by the combined technique, using a master gutta-percha cone and secondarily filling the canal with injected thermoplasticized gutta-percha, will allow the practitioner to decide whether this technique will adequately seal the root canal system from the attachment apparatus.

Progress: Experimental studies completed and data collected. Statistics need to be computed. Report and conclusions to be written and will submit to Journal of Endodontics.

# Detail Summary Sheet

Date: 6 Oct 87	Prot No.: 87-33	Status: Ongoing
Title: Stereomicroscopic Evaluation of Canal Shape Following Hand, Sonic, and Ultrasonic Instrumentation.		
Start Date: Mar 87	Est Comp Date:	
Principal Investigator(s) Robert J. Loushine, MAJ, DC	Facility: Tingay Dental Clinic, DDEAMC	
Dept/Svc: Dental Activity	Associate Investigators: R. Norman Weller, COL, DC Gary R. Hartwell, COL, DC	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the shape and surface quality of the canal walls following preparation by sonic, ultrasonic, and hand instrumentation.

Technical Approach: 90 canals have been instrumented; 15 hand technique vs 15 sonic air (sonic); 15 hand technique vs 15 endostar (sonic); 15 hand technique vs 15 cavi-endo (ultrasonic).

Progress: All teeth have been sectioned. Two raters have rated the canal shapes in each section and the values tabulated. The numbers are ready for statistical analysis.

# Detail Summary Sheet

Date: 8 Oct 87		Prot No.: 87-46		Status: Ongoing	
Title: Presence of Pneumocystis carinii Organisms in the Oral Cavity and Correlation with the Walter Reed Staging Classification of HIV Positive Patients					
Start Date: Jul 87			Est Comp Date: Mar 88		
Principal Investigator(s) James N. Hamilton, MAJ, DC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Dental Activity, Clinical Investigation			Associate Investigators: Stevan H. Thompson, CPT, DC Michael J. McQuade, COL, DC Michael J. Scheidt, COL, DC Kent M. Plowman, LTC, MC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the presence of Pneumocystis carinii in the oral cavity and correlate the findings with the severity of periodontal disease and the incidence of Pneumocystis carinni pneumonia in HIV positive patients. The hypothesis is that the oral cavity is a reservoir for the Pneumocystis carinii organism in HIV positive patients and may predispose these immunocompromised patients to Pneumocystis carinii pneumonia.

Technical Approach: Cytology smears from the oral cavity will be examined for the presence of Pneumocystis carinii. The smears will be taken from the tongue, buccal mucosa, pharynx, and dental plaque from HIV positive patients and HIV negative patients. The findings will be correlated to different stages of dental health including healthy gingiva, gingivitis, and periodontal disease.

Number of subjects enrolled during reporting period: 6

Progress: As of this time six HIV patients Walter Reed Classification 4 to 6 have been examined with cytological smears for Pneumocystis carinii in the study sites. One HIV 6 patient has had intraoral photographs taken for presentation purposes.

# Detail Summary Sheet

Date: 3 Aug 87		Prot No.: 85-26		Status: Terminated	
Title: The Interrelationship of Exercise and Fitness During Pregnancy and the Postpartum Period.					
Start Date: Aug 85			Est Comp Date:		
Principal Investigator(s) Dawn E. Light, MD, CPT, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Family Practice/Physical Therapy/ Occupational Therapy			Associate Investigators: Gaetano G. Scotece, CPT, SP Paula J. Raevsky, CPT, SP		
Key Words: Exercise, Fitness, Pregnancy, Postpartum					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To assess whether the maintenance of an organized exercise program during the second half of pregnancy with result in improved fitness in the postpartum period. This study is a prospective trial of active duty and dependent women, ages 18 to 35, whose pregnancies are uncomplicated.

Technical Approach: Randomly assigned exercise and control groups will be given a baseline fitness test at 16 weeks gestation and will have this test repeated at 32 weeks gestation and six weeks postpartum. The program for the exercise group involves aerobics (aquatics), stretching exercises and non-water aerobic exercises.

Number of subjects enrolled to date: 33

Number of subjects enrolled during reporting period: 0

Progress: Unable to solicit enough subjects for evaluation. Project has been terminated.

# Detail Summary Sheet

Date: 28 Oct 87		Prot No.: 87-27		Status: Ongoing	
Title: Lower Extremity Stress Fractures: A Demographic Review of Fort Gordon Military Morbidity and an Analysis of the Role of Crutches.					
Start Date: Mar 87			Est Comp Date:		
Principal Investigator(s) Mark D. Robinson, MD, CPT, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Family Practice			Associate Investigators: Claude E. Lett III, CW3, PA		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To analyze all patients with potential lower extremity stress fractures presenting for care at TMC #1, and determine if healing time, and consequently, the time to return to full duty can be shortened by the use of crutches.

Technical Approach: Analysis will be directed toward identifying the historical and demographic features of: age, sex, anatomical location of fracture, prior athletic training, medication use, whether injury occurred in basic training or on Ft Gordon, and whether medical profiles are violated. Patients will be randomly assigned to treatment either with or without crutches on the initial visit.

Study was temporarily halted in June until October pending approval of completed informed consent form, which has been achieved.

Number of subjects enrolled to date: 100

Progress: Of the subjects enrolled 19 were lost to followup after initial visit; 23 experienced relief of symptoms within two weeks and did not undergo bone scanning, of these 15 were treated with crutches, 8 without crutches. Fifty-eight subjects underwent bone scanning, 42 +, 16 - for stress fracture. Of the 42 positive for stress fracture:

## With Crutches (20)

7 referred to Orthopedics  
  
12 Completed protocol  
(Average days to healing: 46)  
  
1 Lost to followup

## Without Crutches (22)

6 referred to Orthopedic  
  
7 Completed protocol  
(Average days to healing: 55)  
  
9 lost to followup

There appears to be a benefit to the use of crutches, however, due to many patients lost to followup we need to enroll more patients for data to become statistically significant.

# Detail Summary Sheet

Date: 1 Oct 87		Prot No.: 87-53		Status: Ongoing	
Title: Infant Exposure to Tobacco Smoke Pollution: A Trial of Educational Intervention					
Start Date: Oct 87			Est Comp Date: Apr 89		
Principal Investigator(s)			Facility:		
Wiley A. Smith, MD, MAJ, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Family Practice			Ronald J. Edwards, MD, LTC, MC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) What is the correlation between an infant's urinary cotinine and the reported smoking habit of the parents? 2) Do mothers who decrease or stop smoking during pregnancy resume smoking afterwards? 3) Are infants who are breast fed by smoking mothers exposed to more nicotine than those who are not? 4) Are parents knowledgeable of the adverse effects of tobacco smoke on their infants? 5) Can an educational intervention reduce infant exposure to tobacco smoke? 6) Can an educational intervention increase parental knowledge of adverse effects?

Technical Approach: Information from the parents will be gathered, to include the parent's personal smoking habits, smoking during pregnancy, breastfeeding, and awareness of potential health consequences. This data will be correlated with an objective measurement of tobacco smoke exposure, the urinary cotinine to creatinine ratio. Infants and their families will be randomly assigned to either an intervention or control group.

Progress: Study approved in September. No reportable data available.

# Detail Summary Sheet

Date: 9 Oct 87		Prot No.: 78-38		Status: Ongoing	
Title: Efficacy of Immunotherapy for Systemic Allergic Reaction to Imported Fire Ant Stings. Human Immunologic Reactivity to Fire Ant Antigens.					
BB IND 1452, Part II, III					
Start Date: Feb 85			Est Comp Date:		
Principal Investigator(s)			Facility:		
Antonio L. Bunker-Soler, LTC, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Immunology			Robert B. Rhoades, MD, Medical College of Georgia		
Key Words:			Chester T. Stafford, MD, Medical College of Georgia		
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Mar 87	
				Review Results Continue	

Study Objectives: a. To ascertain the relative efficacy of immunotherapy with whole body extracts and venom compared to placebo in the treatment of systemic hypersensitivity to stings of the imported fire ant.

b. To ascertain the natural history of imported fire ant hypersensitivity and to identify possible subgroups who may undergo spontaneous desensitization and not require immunotherapy.

Technical Approach: Experimental design: Patients found to be allergic to fire ants by history and laboratory parameters will be placed on placebo, whole body extract or venom. After approximately eight weeks, patients will be hospitalized for repeat lab parameters and challenge to fire ant bite. Depending on outcome, adjustment of treatment will be done accordingly.

Number of subjects enrolled to date: 7

Number of subjects enrolled for reporting period: 4

Progress: Revised consent form was approved. Also approved was addendum of incorporation of Vespa venom products to study. Two subjects have completed the protocol with no adverse reactions.

# Detail Summary Sheet

Date: 1 Oct 87      Prot No.: 83-22      Status: Ongoing  
 Title: Use of Isotretinoin in Prevention of Basal Cell Carcinoma

Start Date: Feb 85	Est Comp Date:	
Principal Investigator(s) Marshall A. Guill, MD, COL, MC	Facility: Eisenhower Army Medical Center	
Dept/Svc: Medicine/Dermatology	Associate Investigators: James K. Aton, Jr., MD, COL, MC John R. Cook, MD, COL, MC	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 87 Review Results Continue

Study Objective: To evaluate the effectiveness of low dosage levels of isotretinoin in reducing the incidence of basal cell carcinomas in a high risk population. To examine possible side effects associated with long term administration of low doses of isotretinoin.

Technical Approach: Patients with two or more basal cell carcinomas (BCC) in the past five years are eligible for inclusion in the study. They must be between the ages of 40 and 75 and incapable of bearing children. After a thorough physical examination, including basic laboratory data, participants are randomized to either the treatment group of the placebo group. The medication is provided by the National Cancer Institute and is double-blinded. Participants take medication for 36 months, continuing to be followed for the following 24 months for a total of 60 months in the study. We hope to enroll a total of 150 patients during the 18-month enrollment period.

Funding: A total of \$48,800 was provided this fiscal year by NCI. Included in this amount is the \$11,000 granted for the purchase of the microcomputer and the laser printer. Since the recruitment has ended, our funding will decrease substantially for the remainder of the study.

Number of subjects enrolled to date: 131  
 Number of subjects enrolled for reporting period: 35

Progress: We continued to accrue patients through 26 June 1987 when recruitment ended. We have a total of 131 randomized patients which we feel is very representative of the national total of 981 (eight study centers). The additional 35 patients were recruited from the Ft Jackson, Columbia, SC area and from the results of a skin cancer screening clinic held in November 1986. We have also recruited more patients from the Ft Stewart/HAAF area and make biannual visits to HAAF, Savannah, GA in February and August.

We continue to get excellent ancillary support from our Pathology and Radiology Departments at DDEAMC as well as the regional hospitals at Ft McPherson, Ft Stewart and HAAF. There have been some problems encountered

since our clinic moved outside the main hospital in June 1987. Patients now have to go to the main hospital for x-ray, lab, and pharmacy support. We have also lost our access to the lab computer which was invaluable in getting results from lab work done at DDEAMC and other medical treatment facilities. The physical problems (poor lighting, inadequate wiring and the general need for painting and renovating) in the older two story "temporary" WW II building are being addressed and hopefully upgrading will begin soon.

The laser printer is on board (awaiting a cartridge) and the microcomputer should be on board within one to two months. A copy machine has been purchased with study funds and is presently on post awaiting delivery to the clinic.

We have continued to experience a few adverse reactions. Within the past year, we have removed three subjects from medicine for various reasons: one patient had recurrent TIAs and thrombophlebitis and had been placed on Coumadin and was taken off medicine at his internist's request; another patient has glaucoma and requested to discontinue the medicine since he did not want to confuse any possible side effects with new glaucoma medicine (he was having trouble with regulation of intraocular pressure and had stopped taking his medicine on his own for almost four months); and another patient had been on dose modification to one pill for several months with improvement of nausea (he was diagnosed as hiatal hernia) and when the nausea reoccurred, he requested to permanently discontinue the study medicine. We have had three more patient deaths - two from myocardial infarctions and one from metastatic cancer (liver) which was diagnosed after entering into the study. Another patient is terminally ill with metastatic cancer of the lungs and bowel that was diagnosed in June 1987. One patient has dropped out of the study after he became angry when an Army psychiatrist who documented in his medical record that he was "malingering." He chose to sever all his ties with the Army even though he had no complaints with the Dermatology Service. This same patient had been off medication for a few months earlier in the year while undergoing a neurological and psychiatric workup after CT scan revealed cortical atrophy. In summary, of 131 patients, 15 are off medication (including four deaths). Six are on dose modification for non-cutaneous side effects to include elevated SGOT, elevated triglycerides, arthralgias and nausea. Five patients are on dose modification to one pill also for cutaneous side effects to include dry ocular and nasal mucosa and chapped lips and skin. The first patient to be enrolled in the study at BAMC who was subsequently transferred to DDEAMC has reached the three year mark in the study and is no longer on the medication. We have transferred one patient to WRAMC and one to BAMC and have received another transfer from BAMC and one from Portsmouth Naval Hospital.

We continue to find the study challenging. The compliance with appointments and medications remains high. We hope to maintain this interest and compliance throughout the remainder of the study. The change in our physical facility has impacted on our accessibility to other clinics and departments that we use as consultants when our patients have problems. These problems were foreseen, but are still very difficult and inconvenient.

# Detail Summary Sheet

Date: 8 Oct 87		Prot No.: 85-23		Status: Terminated	
Title: Effect of Ketoconazole Therapy on the Susceptibility of Enteric Fungi to Amphotericin B and Ketoconazole.					
Start Date: June 1985			Est Comp Date: June 1986		
Principal Investigator(s) Ruth Marie E. Fincher, MD			Facility: Eisenhower Army Medical Center, Medical College of GA		
Dept/Svc: Medicine/Dermatology			Associate Investigators: Marshall Guill, MD, LTC, MC		
Key Words:			John F. Fisher, MD		
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To ascertain ketoconazole and AMB susceptibility patterns of stool fungal isolates in patients prior to and following treatment with ketoconazole.

Technical Approach: Stool specimens are obtained before and after treatment with ketoconazole. These are then cultured and fungal isolates are tested for amphotericin B susceptibility.

No excess Eisenhower manpower is required for the study. All cultures and sensitivity tests are done at the Medical College Laboratories.

No funding is required.

Number of subjects enrolled to date: 8

Number of subjects enrolled during reporting period: 0

Progress: Terminated due to lack of patient compliance for after treatment specimen.

# Detail Summary Sheet

Date: 7 Oct 87	Prot No.: 85-24	Status: Completed
Title: Extravascular Penetration of Antimicrobial Agents in New Zealand White Rabbits.		
Start Date: June 1985	Est Comp Date:	
Principal Investigator(s) Robert E. Morrison, MD, COL, MC	Facility: Eisenhower Army Medical Center	
Dept/Svc: Medicine Clinical Investigation	Associate Investigators:	
Key Words: Antimicrobial agents Beta-lactam antibiotics		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: 6,200	Periodic Review Results

Study Objective: To examine new antimicrobial agents to determine the comparative ability to penetrate into intraperitoneal and subcutaneous extravascular compartments.

Technical Approach: Sterile plastic capsules will be implanted intraperitoneally and subcutaneously into New Zealand white rabbits. Six weeks following surgery, a three-day therapy will be initiated by i.p. injection to achieve equilibrium plasma levels. Drug profile in plasma and capsule will be monitored. Pharmacokinetic evaluation of drug plasma levels and drug capsule levels will be performed.

Progress: Comparison of two-compartment pharmacokinetic parameters of aztreonam in normal rabbits with an implanted capsule received only aztreonam (group 1), and rabbits with an implanted capsule and coadministered with amoxicillin (group 2). The coadministration of amoxicillin seemed to have no significant effect on the total aztreonam accumulated in the extracellular fluids from 15 to 300 minutes post treatment. On the other hand, the coadministration of amoxicillin and aztreonam caused a significant ( $p > 0.05$ ) increase in the elimination half life of both alpha and beta phase. The distribution volume ( $V_c$  and  $V_d$ ) of aztreonam was also higher than those obtained in control group (group 1). Aztreonam shows a rapid initial distribution phase and a slow elimination phase. The elimination half life of the beta phase was in hours while the alpha phase was within 3 to 15 minutes. The total body clearance of aztreonam when administered with amoxicillin was also decreased. The effect of amoxicillin on aztreonam kinetics may be due to an effect on aztreonam liver metabolism, protein binding or on its elimination process. The hepatic clearance of  $\beta$ -lactam antibiotics is dependent on and may reflect liver metabolism or biliary excretion. In addition, it is documented that liver disease increases the volume of distribution of  $\beta$ -lactam antibiotics by several mechanisms. This may indicate that the attenuation in aztreonam kinetics may be associated with an effect of CA on liver perfusion or aztreonam liver metabolism. This may conclude that dose adjustment might be necessary in combined amoxicillin and aztreonam treatment.

# Detail Summary Sheet

Date: 1 Oct 87 Prot No.: 86-2 Status: Completed  
 Title: Comparison of Test for the Diagnosis of Imported Fire Ant (IFA) Allergy.

Start Date: Feb 86	Est Comp Date: Feb 87
Principal Investigator(s) Antonio L. Bunker-Soler, LTC, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Medicine/Allergy-Immunology	Associate Investigators: Chester T. Stafford, MD, Medical College of Georgia John E. Moffitt, MD Donald F. Hoffman, PhD
Key Words:  Fire Ant Allergy	Periodic Review Results
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:

Study Objective: To compare the validity and reliability of currently available in vivo and in vitro tests with newly developed test using standardized allergens for the diagnosis of IFA allergy.

Technical Approach: Patients referred to the Allergy Services of Eisenhower and the Medical College of Georgia into two groups. Those with no history of systemic reaction to fire ants served as the control group and the comparison group consisted of patients with a history of such reactions. Both were tested (in vivo studies) to whole body extract from Greer Labs and aqueous extract available at Eisenhower. Blood was obtained for RAST (in vitro studies) to whole body tests performed by Mayo Med Lab and aqueous venom by Dr. Donald Hoffman, East Carolina University School of Medicine.

Manpower: technical assistance provided by personnel in Allergy Services, MCG and Eisenhower Army Medical Center.

Number of subjects enrolled to date: 39

Number of subjects enrolled during reporting period: 3

No adverse reactions.

Progress: The specificity and sensitivity of skin test reactivity to fire and (IFA), whole body extracts (WBE) and IFA venom was compared to RAST whole body extract and RAST venom in the diagnosis of fire ant allergy. Study groups consisted of 18 fire ant allergic patients and 21 insect non-allergic controlled subjects.

All fire ant allergic patients had positive skin testing to both whole body extract and venom. Seven of 21, or 33%, control subjects had positive skin testing to whole body extract, and six of 21, or 29%, reacted to venom. Commercial whole body extract RAST was positive in 10 of 18, or 56%, and venom RAST was positive in 16 of 18 sera from imported fire ant allergic patients. Two of 21, or 10%, control subjects had positive whole body extract RAST and five of 21, or 24%, had positive venom RAST.

86-2 Continued

The sensitivity and specificity of whole body extract skin testing, venom skin testing and venom RAST did not differ significantly.

Whole body extract RAST was significantly less sensitive than other diagnostic methods.

Bunker-Soler A: Comparison in vivo and in vitro test in the diagnosis of imported fire ant allergy. Southeastern Allergy Assn Mtg, Oct 1986.  
First prize research competition at Assn Military Allergists, Harold S. Nelson Symposium, Feb 87, and Dura Pharmaceutical Award for excellence in postgraduate research, Am Academy Allergy Immunology, Feb 87.

Submitted to Journal Allergy Clinic Immunology.

# Detail Summary Sheet

Date: 9 Oct 87		Prot No.: 87-1		Status: Ongoing	
Title: Causes of Transient Myocardial Ischemia in Asymptomatic and Symptomatic Patients with Coronary Artery Disease.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
George S. Rebecca, MD, LTC, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Cardiology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective:					

Technical Approach:

Progress: Study not yet implemented.

# Detail Summary Sheet

Date: 9 Oct 87		Prot No.: 87-2		Status: Ongoing	
Title: Comparison of Intravenous Abbokinase and Streptokinase in the Treatment of Acute Myocardial Infarction.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
George S. Rebecca, MD, LTC, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Cardiology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective:					

Technical Approach:

Progress: Study not yet implemented.

# Detail Summary Sheet

Date: 9 Oct 87		Prot No.: 87-3		Status: Ongoing	
Title: Evaluation of Dynamic Rate Response Pacing, Incidence of Myocardial Ischemia and Reaction of Epicardial Coronary Arteries.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
George S. Rebecca, MD, LTC, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine/Cardiology					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective:					

Technical Approach:

Progress: Study not yet implemented.

# Detail Summary Sheet

Date: 28 Oct 87		Prot No.: 87-7		Status: Ongoing	
Title: The Detection of Epithelial Dysplasia by Light and Scanning Electron Microscopy in Patients with Barrett's Esophagus					
Start Date: Dec 86			Est Comp Date: Dec 88		
Principal Investigator(s) Howard M. Rosen, MD, COL, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Medicine/Gastroenterology Service			Associate Investigators: William T. Brand, Jr., MD, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: 1) To utilize light microscopy and scanning electron microscopy to confirm the presence of metaplasia, and 2) to identify a subgroup of patients with Barrett's esophagus with severe dysplasia and correlate the light microscopic findings for metaplasia and dysplasia with the scanning electron microscopic features.

Technical Approach:

Number of subjects enrolled to date: 2

Progress: Two samples have been processed. Patient accrual has been slow.

# Detail Summary Sheet

Date: 1 Oct 87		Prot No.: 87-49		Status: Ongoing	
Title: A Survey of the Sexual Practices of HIV Antibody Seropositive Patients					
Start Date: Oct 87			Est Comp Date: Jul 88		
Principal Investigator(s)			Facility:		
Roberto N. Nang, MD, CPT, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Medicine					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine among a group of patients that are HIV antibody seropositive: 1) how prevalent are the patient's sexual orientation to homosexuality vs bisexuality vs homosexuality based on Kinsey's graded scale of sexual orientation; 2) how many different partners and how many different sexual encounters they may have had within a given time period; 3) how common a variable is: a) anal (receptive vs insertive) intercourse, and b) oral (passive vs active participation among these patients; 4) how common a variable among these patients is involvement with a prostitute; 5) after these patients were informed of their HIV seropositivity and after being informed of its consequences, what, if any, changes have been made in their sexual practices.

Technical Approach: The responses of the subjects who take the HIV medical survey will be summarized and compared using both descriptive and inferential statistical analyses. Associations between various groups will be examined (t-test for one-way analysis of variance, Chi-square, Pearson r correlation coefficients, and nonparametric Spearman rank order correlation.

Progress: Study approved in September, no reportable data available.

# Detail Summary Sheet

Date: 1 Oct 87		Prot No.: 87-51		Status: Ongoing	
Title: The Effectiveness of Metoclopramide to Improve Colonic Visibility in Patients Receiving Night Prior Colonic Lavage: A Double Blind Randomized Study					
Start Date: Oct 87			Est Comp Date: Oct 88		
Principal Investigator(s) Peter R. McNally, DO, MAJ, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Medicine/Gastroenterology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To evaluate if the addition of metoclopramide the night prior to colonoscopy preparation can improve colonic visibility and shorten procedure time.

Technical Approach: All patients will receive either metoclopramide or placebo. Visibility parameters will be assessed in accordance with an established scheme. Duration of procedure will be recorded for all patient.

Progress: Study approved in September. No reportable data available.

# Detail Summary Sheet

Date: 1 Oct 87		Prot No.: 84-73		Status: Ongoing	
Title: Transition into Military Nursing: An Evaluation of A Preceptorship Program.					
Start Date: Sep 84			Est Comp Date:		
Principal Investigator(s) Bruce C. Allanach, LTC, AN			Facility: Eisenhower Army Medical Center		
Dept/Svc: Nursing			Associate Investigators: Bonnie Jennings, MAJ, AN		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: Examine those factors which facilitate the integration of new ANC officers into a hospital nursing milieu. Determine whether locus of control, as well as affective states of anxiety, hostility, and depression are prime factors in the integration of new ANC officers. Develop a protocol which examines whether there are any differences among nurse preceptees within the same preceptorship program who are judged to be a success. The literature reflects that participants in such programs evaluate the programs as successful. Locus of control and multiple affective states may underscore differences in participants evaluation of a program as successful. A preceptorship program is geared to ease transition phenomenal among new nurses who are prone to affective states associated with change such as anxiety, hostility, and depression.

Technical Approach: The data collection for each preceptee occurs over a period of 26 weeks. The plan is evaluation research using a time-series design. The effects of the program will be examined against the goals through a series of measurements during week 1, 4, 8, 9, 13, and 24 after arrival at DDEAMC. These points of time include before the program begins, during the program, and after the program ends. The principal investigator administers the tools.

Subjects enrolled to date: 42  
Subjects enrolled for reporting period: 0

Progress: All data has been coded and sent to associate investigator for entry into computer for data analysis.

# Detail Summary Sheet

Date: 15 Sep 87		Prot No.: 86-25		Status: Completed	
Title: The Effects of the Heating and Humidifying of Anesthetic Gases on the Maintenance of Body Temperature: A Replication.					
Start Date: Aug 86			Est Comp Date: Jan 86		
Principal Investigator(s) Jacqueline Newman, CPT, AN			Facility: Eisenhower Army Medical Center		
Dept/Svc: Nursing/Anesthesia & Operative Svc			Associate Investigators:		
Key Words: Hypothermia, Heat, Humidity					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To investigate the effects of the heating and humidifying of inspired anesthetic gases to 40°C and 100% relative humidity on body temperature of adults undergoing open abdominal surgery under general anesthesia.

Technical Approach: Temperature is measured using the aural canal site and esophageal site. An electronically controlled heater humidifier system is inserted in the breathing circuit of the experimental group. Airway temperature is monitored at the endotracheal tube site.

Number of subjects enrolled to date: 6

No adverse reactions have been encountered.

Progress: Study was completed, however, investigator PCS'd and did not submit a final report.

# Detail Summary Sheet

Date: 23 Sep 87		Prot No.: 87-38		Status: Completed	
Title: The Effects of Preparatory Information on Anxiety Levels During Intravenous Catheter Insertion					
Start Date: Jun 87			Est Comp Date: Aug 87		
Principal Investigator(s)			Facility:		
Carolina di Donato-Gonzalez, Grad Student			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Nursing					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine if sensory information instruction is more effective than standard procedural information in reducing the level of anxiety experienced by patients during IV catheter insertion.

Technical Approach: The Spielberger State-Trait Anxiety Inventory (STAI) for state anxiety was the instrument used to measure state anxiety. the randomized post-test only design tested the following hypothesis: subjects receiving sensory information instruction prior to IV insertion will have lower state anxiety, as measured by the STAI Form Y-1, than those subjects receiving only standard preparatory information. Subjects were randomly assigned to either the experimental group (n=17) or the control group (n=17). Prior to IV insertion all subjects listened to a pre-recorded audio-taped message consisting of either sensory or standard preparatory information. Subjects were then asked to complete the STAI Form Y-1 for state anxiety.

Number of subjects enrolled for reporting period: 34

Progress: The t-test for independent means procedure revealed no significant difference ( $p=.05$ ) in the mean anxiety scores between the two groups. Therefore, the hypothesis was rejected. This finding indicates that in this study, the state anxiety levels of subjects receiving sensory information did not differ from the state anxiety levels of subjects receiving preparatory information only. Since this finding differs from most results reported in the literature, it would appear that further refinement of the sensory message related to IV insertion is warranted in view of the results of this study.

# Detail Summary Sheet

Date: 23 Sep 87      Prot No.: 87-34      Status: Ongoing  
 Title: Nutrition Education Adherence Trial (NEAT).

Start Date: Mar 87	Est Comp Date: Mar 88
Principal Investigator(s) Patricia Krause, MAJ, SP	Facility: Eisenhower Army Medical Center
Dept/Svc: Nutrition Care Division	Associate Investigators: Holly A. Dieken, R.D.
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: 1. To identify different learner types by using a composite score from two scales; the diabetes locus of control scale and the preference for learning style inventory. 2. to evaluate the degree of regimen adherence attained when different learners are exposed to one of four treatment programs. The education programs are based on degree of structure in education and frequency of reinforcement.

Technical Approach: Patients who meet the screening criteria and consent to participate will complete two evaluation instruments. Instrument scores are used to determine learner type. Patients are then randomized to one of four treatment groups. Patients attend two 2-hour classes on consecutive weeks. All patients attend the same first class then are split into two different classes for the second class. Based on the treatment group, patients follow either a high or low reinforcement program. On the sixth and sixteenth week of the study patients have blood drawn for fasting blood-glucose and glycosylated hemoglobin, patients are also weighed, complete a self-report of adherence, and give a 24 hour dietary recall.

Number of subjects enrolled to date: 5

Progress: Five patients are scheduled to begin the study on 23 September 1987. New groups of patients will enter the study for approximately 10 weeks or until a sample of 60 is attained. The last patient should complete the study sometime in February 1988.

# Detail Summary Sheet

Date: 7 Oct 87 Prot No.: 84-4 Status: Ongoing  
 Title: Metastatic Adenocarcinoma of Unknown Primary Site.

Start Date: Nov 83	Est Comp Date: May 85
Principal Investigator(s) Ricky Reaves, M.D., CPT, MC Phyllis Brewer Jack A. Horner	Facility:  Eisenhower Army Medical Center
Dept/Svc: Pathology Clinical Investigation	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To determine whether or not the primary site of a metastatic adenocarcinoma of unknown origin can be determined with a high degree of accuracy.

Technical Approach: (1) Gathering cases where primary tumor site is unequivocal.  
 (2) Manpower: Three.  
 (3) Morphometric measurements will be made on tumors from known primary sites (adenocarcinomas only) to determine if a statistically significant difference in microvillus size can be assigned to the various primary organs.

Progress: The frequency with which samples, suitable for inclusion in this study, are submitted is very low. The accumulation of data is continuing, although the data base remains too small for a statistical study.

# Detail Summary Sheet

Date: 30 Sep 87 Prot No.: 86-15 Status: Completed  
 Title: The Effect of Normal Plasma Dilution Upon the Prothrombin Time and Activated Partial Thromboplastin Time of Heparinized Blood.  
 Start Date: Apr 86 Est Comp Date:  
 Principal Investigator(s) Facility:  
 James M. Monihan, M.D., CPT, MC Eisenhower Army Medical Center  
 Dept/Svc: Associate Investigators:  
 Pathology  
 Key Words:

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
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Study Objective: To help delineate the effect of normal plasma dilution on heparin's effects in vitro, thereby improving the ability of the clinical laboratory to evaluate coagulopathic patients.

Technical Approach: Plasma samples are obtained from normal volunteers presenting to the Blood Donor Center. These are then divided into experimental and control groups at random. Baseline PT/APTT tests are then obtained, following which the experimental samples are heparinized with 0.3u sodium heparin per lcc of plasma. The PT/APTT is then repeated. A 1:1 mix of sample with known normal plasma is then performed and a third PT/APTT obtained.

Total number of subjects enrolled to date: 28  
 Number of subjects enrolled during reporting period: 18

Progress: With a total of 28 subjects enrolled, the study was terminated. Data from the first 10 patients appears below:

## Control Group

Patient #	Initial PT/APTT	Post-NaCl PT/APTT	Post-Plasma Dilution PT/APTT
1	12.7/29.4	13.1/28.0	12.1/27.9
2	14.6/32.3	14.7/31.6	12.7/27.9
3	14.2/31.1	14.2/30.4	12.5/28.4
4	15.4/28.6	15.9/29.4	12.7/28.0
5	13.3/29.7	13.4/30.5	12.1/28.9

## Heparinized Group

Patient #	Initial PT/APTT	Post-NaCl PT/APTT	Post-Plasma Dilution PT/APTT
6	13.0/28.3	15.1/61.5	13.0/36.8
7	13.2/30.6	14.6/59.9	13.1/37.3
8	12.8/27.2	15.4/71.2	12.8/40.8
9	12.9/31.3	14.9/67.2	13.4/40.5
10	13.6/29.9	16.1/65.3	13.6/39.7

From this data, it is at least superficially evident that a circulating

86-15 Continued

inhibitor's effect on the APTT may be diminished in vitro by the addition of normal plasma. We have since applied this knowledge to clinical consultations in several cases. At the same time, more advanced coagulation studies have become available. Their availability has made the use of serial APTTs with normal plasma dilutions of less use to our laboratory. While no further studies on this protocol are planned, future work could include comparison of in vitro with in vivo heparinized specimens, as well as the differing effects of different APTT reagents.

# Detail Summary Sheet

Date: 1 Oct 87      Prot No.: 87-40      Status: Ongoing  
 Title: Pathology Applications of X-ray Spectrometric Microanalysis.

Start Date:		Est Comp Date:
Principal Investigator(s) James M. Monihan, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Pathology/Clinical Investigation		Associate Investigators: Jack A. Horner, B.S. Phyllis Brewer
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To utilize specimens obtained during routine surgical and autopsy pathology examinations to gain expertise in applications of x-ray spectrometric microanalysis.

Technical Approach: Tissue specimens without known abnormalities of elemental composition are selected from the daily laboratory workload. These are examined for establishment of baseline spectrometric spectra following the use of various fixatives. These spectra can then be compared against specimens with known or suspected elemental abnormalities.

Manpower demands have been met by the principal and associate investigators alone.

Funding has not required the allocation of any additional funds.

Progress: Up to this point, approximately forty separate examinations have been conducted, the majority for baseline determinations. These have resulted in the acquisition of considerable experience in handling and interpretation of these specimens. We are continuing to acquire specimens, particularly those with known abnormalities.

# Detail Summary Sheet

Date: 1 Oct 87 Prot No.: 85-4 Status: Ongoing  
 Title: Training Laboratory for Neonatal Procedures.

Start Date:	Est Comp Date:
Principal Investigator(s) Thomas M. Martinko, MD, CPT, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Pediatrics, Clinical Investigation	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Sep 87 Review Results Continue

Study Objective: To familiarize residents on rotation through the Department of Pediatrics with endotracheal intubation procedures in the newborn.

Technical Approach: Practice placement of endotracheal tubes. Involves two technicians in Clinical Investigation, staff pediatrician and three to five students.

Progress: Each new group of interns has had the laryngoscopy lab on cats and kittens. It involves providing practice with intubation.

# Detail Summary Sheet

Date: 1 Oct 87		Prot No.: 86-16		Status: Ongoing	
Title: Androgen Responsiveness to LHRH Infusion in Adolescent Females with Polycystic Ovarian Syndrome.					
Start Date: Apr 86			Est Comp Date:		
Principal Investigator(s) Gary L. Francis, M.D., MAJ, MC			Facility:		
Dept/Svc: Pediatrics, Clinical Investigation			Associate Investigators: Alan Getts, MD, MAJ, MC James C. McPherson III, PhD Gary Broadnax, MD, COL, MC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Jul 87 Review Results Continue	

Study Objective: To evaluate this effect over 24 hours, with maximal doses of LHRH (100 micrograms), under conditions where ovarian production alone may be studied (dexamethasone suppression), and by including free testosterone levels, to exclude any interference by changing sex steroid binding globulin levels.

Technical Approach: Blood sampling will be taken for androgen levels following the standard LHRH stimulation test. Population will include all adolescent and young adult women referred for evaluation of hirsutism, oligoamenorrhea, or obesity who have given consent.

Number of subjects enrolled to date: 13

Number of subjects enrolled for reporting period: 9

Progress: Samples following LHRH stimulation have been collected on all and frozen at -70 degrees. Samples from early subjects have been sent for analysis and we are awaiting results so that selective samples from remaining subjects may be run. Preliminary information identifies that androgen levels did increase in these samples and were returned to baseline by 24 degrees. Data on estrodial, testosterone, dihydrate testosterone are pending this month. As soon as these profiles are available, preliminary data will be analyzed and the remainder of the samples assayed.

# Detail Summary Sheet

Date: 1 Oct 87		Prot No.: 86-23		Status: Ongoing	
Title: Androgen Binding and Reductase Activity in Hair Follicles from Hirsute Females.					
Start Date:			Est Comp Date: Jun 88		
Principal Investigator(s) Gary L. Francis, MD, MAJ, MC			Facility: DDEAMC		
Dept/Svc: Pediatrics			Associate Investigators: James C. McPherson III, PhD		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To evaluate the potential role of androgen binding and conversion of testosterone to the more potent androgen dihydrotestosterone, in the pathophysiology of hirsutism.

Technical Approach: Female subjects aged 18-40 will have several facial hairs, body hairs, and pubic hairs removed by traction. Adult female and male normal volunteers will have control samples obtained in an identical fashion. Hair follicles will then be assayed for binding of <sup>3</sup>H-dihydrotestosterone and conversion of testosterone to dihydrotestosterone. Data will then be analyzed as to: a) correlation with hirsutism scores, b) correlation with age, and c) correlation with specific etiology of hirsutism.

Number of subjects enrolled for reporting period: 0

Progress: Radiation use approval has been obtained. Study will be initiated soon.

# Detail Summary Sheet

Date: 1 Oct 87      Prot No.: 86-29      Status: Ongoing  
 Title: Neonatal Galactorrhea and Biologically Active Prolactin Levels.

Start Date:		Est Comp Date:
Principal Investigator(s) Gary L. Francis, MD, MAJ, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Pediatrics, Family Practice, Clinical Inv		Associate Investigators:
Key Words:		James C. McPherson III, PhD William H. Hoffman, MD, MCG
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Jul 87 Review Results Continue

Study Objective: To evaluate the potential role of elevated BA-PRL in the pathogenesis of neonatal galactorrhea and breast engorgement. It will also define a normal range for BA-PRL in human cord blood.

Technical Approach: Infants at birth will have cord blood samples obtained by routine fashion. Samples will be separated and serum frozen for subsequent analysis of PRL by both radioimmunoassay and biological assay. Infants will be examined at the time of their initial discharge, and two-week physical examinations for the presence of galactorrhea as well as breast bud size.

Number of subjects enrolled for reporting date: 16

Progress: Ninety-one newborn infants have been examined for breast bud size and galactorrhea. Of these 16 returned to well baby clinic at the appointed two-week followup interval and had repeat physical exam performed. Almost all subjects evidenced galactorrhea at two weeks. Of these 16 subjects, sufficient blood was available on 11 for assay (3 without galactorrhea and 8 with galactorrhea).

Although there are not yet enough data to statistical significance, RIA appears to correlate with biological assay. Boys have lower ( $282 \pm 60$  ng/ml) prolactin than girls ( $442 \pm 254$  ng/ml) and prolactin levels increase with increasing breast size. No difference is yet apparent in the group with galactorrhea compared to those without.

Presently, another 25 samples are frozen for assay to add sufficient data to allow more definitive comparisons.

# Detail Summary Sheet

Date: 1 Oct 87	Prot No.: 87-48	Status: Ongoing
Title: Biobehavior and Family Psychodynamics in Precocious and Pseudo-precocious Puberty		
Start Date: Sep 87	Est Comp Date: Sep 89	
Principal Investigator(s) Gary L. Francis, MD, MAJ, MC	Facility: Eisenhower Army Medical Center	
Dept/Svc: Pediatrics Psychiatry & Neurology	Associate Investigators: Peter S. Jensen, MD, MAJ, MC	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To evaluate the frequency and nature of psychological disturbances in patients and parents of patients with precocious puberty, precocious thelarche and precocious adrenarche.

Technical Approach: In addition to the survey, correlations will be made of such disturbances to the diagnosis, the presence and absolute level of gonadotropin and estrogen levels, the presence and absolute level of androgens, the degree of pubertal development, the presence of menarche, and the degree of advancement of bone age.

Progress: Study approved in September, no available data.

# Detail Summary Sheet

Date: 1 Oct 87	Prot No.: 84-1	Status: Ongoing
Title: The DDEAMC Alcohol Residential Treatment Facility Patient Outcome Study.		
Start Date: Oct 83	Est Comp Date:	
Principal Investigator(s) Peter S. Jensen, M.D., MAJ, MC Daniel Hendricks, M.D., CPT, MC Lou Van Osdel, M.D., LTC, MC	Facility: Eisenhower Army Medical Center	
Dept/Svc: Psychiatry and Neurology	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic May 87 Review Results Continue

Study Objective: To better understand alcoholism and its treatment by assessing some of its biological, psychological, and social concomitants, and determining their diagnostic and prognostic validity.

## Technical Approach:

1. Summary of Experimental Design: This study is prospective in design. Measures of the above mentioned variables will be taken prior to, and upon completion of, treatment. Additionally, follow-up questionnaires are to be completed by the patient, spouse, and patient's commander at intervals of three, six, nine, twelve, and twenty-four months after discharge. Relationships will be measured using analysis of variance and analysis of covariance procedures.
2. Manpower: Personnel required to gather, collate, and interpret the data are, at a minimum, one 91G Behavioral Science Specialist, one Medical Records Technician, and one Clinical Psychologist.
3. Funding: Not applicable.
4. Number of subjects enrolled to date: 600
5. Number of subjects enrolled during reporting period: 140
6. Adverse reactions: None.

Progress: Data collection continues.

# Detail Summary Sheet

Date: 15 Sep 87		Prot No.: 84-28		Status: Ongoing	
Title: Reliability and Agreement of Reports of Children's Symptoms.					
Start Date: Apr 84			Est Comp Date:		
Principal Investigator(s) Peter S. Jensen, MD, MAJ, MC Stephen N. Xenakis, MD, COL, MC			Facility:  Eisenhower Army Medical Center		
Dept/Svc: Psychiatry-Neurology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Mar 87 Review Results Continue	

Study Objective: To examine the effects of parent and child gender and parental depressive symptoms on the reliability and agreement of children's and parents' reports of children's symptoms and behavior problems.

Technical Approach: (1) One hundred 2-parent families will be selected from on-post housing lists to participate in a study of children's depressive symptoms. To be eligible, families must have a child age 8-12. Also, 100 parents and children who are referred to the Child, Adolescent and Family Psychiatry Service at DDEAMC will also participate in the study. Both groups of families will be compared vis a vis their reports of children's depressive symptoms (Scales used are well-standardized instruments including the Child Behavior Checklist, the Child Depression Inventory, and the Beck Depression Inventory). Reliability and agreement between mother's, father's and children's reports will be analyzed to determine how these indices are affected by sex of parent and child, and depression in the parent.

- (2) Manpower required is limited to the two current principal investigators.
- (3) Funding required is to provide computer support and statistical analysis.
- (4) No adverse reactions.
- (5) Subjects enrolled to date: 200
- (6) Subjects enrolled for reporting period: 60

Progress: Data analysis is complete. Three papers have been written and three more are in progress. The protocol will be amended to allow additional subjects to be accrued since Ft Gordon post officials (Command) wish to examine changes over time in symptom levels in post families.

# Detail Summary Sheet

Date: 2 Oct 86		Prot No.: 85-30		Status: Ongoing	
Title: Family Risk and Protective Factors: A Prospective Study of Obstetric Patients and Their Families.					
Start Date: Aug 85			Est Comp Date:		
Principal Investigator(s) Peter S. Jensen, M.D., MAJ, MC Stephen N. Xenakis, M.D., LTC, MC			Facility:  Eisenhower Army Medical Center		
Dept/Svc: Psychiatry-Neurology/Social Work Service			Associate Investigators: Kent M. Plowman, MD, LTC, MC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Jul 87 Review Results Continue	

Study Objective: This study will determine the additive effects of stress, lack of social supports, parental history, parental coping skills, and marital communication on complications of pregnancy in the mother and newborn, and effects of these factors on the child's growth and development.

Technical Approach: One hundred nulliparous women in the first or second trimester of pregnancy and their husbands will be invited to participate in the study. Subjects and spouses will complete surveys to determine their level of social supports, stress, coping skills, marital relationships, etc. These families will be followed prospectively through the course of pregnancy, into the child's first year of life. Statistical analyses will be performed to assess the relationship between interior (stress, supports, coping, etc.) variables and outcome measures (complications of pregnancy, child's growth and development, frequency of illness, etc.).

Number of subjects enrolled to date: 35  
Number of subjects enrolled for reporting period: 8

Adverse reactions: None.

Progress: No reportable data available.

# Detail Summary Sheet

Date: 1 Oct 87		Prot No.: 87-10		Status: Ongoing	
Title: Neuropsychiatric and Psychosocial Aspects of HIV Disease.					
Start Date: Oct 87			Est Comp Date:		
Principal Investigator(s)			Facility:		
Louis Duchin, MD, CPT, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Psychiatry & Neurology			Stephen Xenakis, MD, COL, MC		
Key Words:			Peter S. Jensen, MD, MAJ, MC		
			Fred Tamayo, MAJ, MS		
Accumulative MEDCASE		Est Accumulative		Periodic	
Cost:		OMA Cost:		Review Results	

Study Objective: To evaluate neuropsychiatric/psychosocial/unit functioning of HIV positive soldiers.

Technical Approach: Self report, rater report, neuropsychiatric questionnaires/evaluations. No funding or personnel assigned as yet.

Number of subjects enrolled to date: 0

Progress: Study not yet implemented.

# Detail Summary Sheet

Date: 23 Jul 87		Prot No.: 87-14		Status: Completed	
Title: Job Performance and Job Satisfaction in the Pregnant Soldier: A Comparison of Her Assessment With That of Her Immediate Supervisor.					
Start Date:			Est Comp Date:		
Principal Investigator(s) Elaine H. Correnti, MD, CPT, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Psychiatry & Neurology			Associate Investigators: Peter S. Jensen, MD, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To identify stressors in the work environment which detract from job satisfaction and job performance, and suggest means by which undue stressors may be alleviated.

Technical Approach: Pregnant soldiers were asked to rate their job performance, job satisfaction, co-worker support and satisfaction. Additionally, they responded to statements concerning Army support of pregnant soldiers and the impact pregnancy has on the effectiveness of the Army. Supervisors responded to 16 corresponding statements regarding the pregnant soldier's job performance and job satisfaction as well as the support offered to her both before and during the pregnancy.

Number of subjects enrolled: 33

Progress: Statistical analysis of 33 pregnant soldier-supervisor pairs revealed essentially no difference between the two groups in how the work situation was viewed prior to the pregnancy. Significant differences, however, existed between the soldiers and their supervisors regarding their perceptions of supervisor, co-worker and Army support during the pregnancy. Although the pregnant soldier did not appear to feel less supported in her work environment during the pregnancy than before, she did not appreciate the increase in support that was perceived by the supervisor. She was more likely to see the Army as nonsupportive than was her supervisor. Interviews of 30 pregnant soldiers suggest that they and their supervisors defined support differently, and this difference in perception may have negative implications for the optimal utilization of servicewomen during pregnancy. Further research is indicated to clarify the types of support needed by this group of soldiers. This represents a possible focus for involvement by mental health professionals in the establishment of educational programs, and other supportive interventions, for both the pregnant soldiers and their supervisors.

# Detail Summary Sheet

Date: 23 Jul 87      Prot No.: 87-15      Status: Terminated  
 Title: The Home Environment Questionnaire: A Validity Study.

Start Date:		Est Comp Date:
Principal Investigator(s) Sharron K. Schreiber, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Psychiatry & Neurology/Psychology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
Study Objective:		

Technical Approach:

Progress: Project terminated at investigator's request, study was not implemented.

# Detail Summary Sheet

Date: 23 Jul 87		Prot No.: 87-31		Status: Completed	
Title: Incest: Understanding its Factors on the Military Family.					
Start Date: Mar 87			Est Comp Date: May 87		
Principal Investigator(s) Cesar Y. Figueroa, MD, CPT, MC			Facility: MEDDAC, Ft Stewart, GA		
Dept/Svc: Psychiatry & Neurology			Associate Investigators: Peter S. Jensen, MD, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To analyze the problem of incest within the military system and how these factors compare with similar parameters studied in control families and families where other problems had been identified.

Technical Approach: Ten families in which incest was reported and documented participated in the study. The cases were reviewed retrospectively and their current family and social situation evaluated. The families were asked to complete questionnaires. The results were compared to the data available on the sample of control families and families of children with Attention Deficit Disorder (ADD).

Progress: The low scores obtained on the children's self-assessments regarding feelings of depression and anxiety are likely to respond to their previous experiences with a system which, in many cases, disrupted the family structure and appeared threatening to the survival of the family. These children might fear that further complaints could lead to additional family crises; so it is important for them to minimize any ongoing problems. The parental self-perception of significant psychiatric symptomatology cannot be ignored. Often the non perpetrator parent is left out by the system: both the child and the perpetrator are provided with immediate help, while the other parent is left with the task of being the main support for a family structure which is rapidly falling apart. The stress to which that parent is exposed can sometimes become unbearable, with the inevitable result of the development of psychiatric symptoms. Another relevant observation was made: there is a subtle resistance on the part of the mental health system to effectively deal with incest cases. In spite of the outstanding effort and great cooperation the staff provided to the investigators, only ten cases completed the study, in a service where more than 40 cases of sexual abuse to children were reported last year. In all the cases the appointed families responded well and actively cooperated with the investigators, in many instances it was the system which failed to identify appropriate cases. Further studies are to help to identify the various needs of the military families are necessary.

# Detail Summary Sheet

Date: 1 Oct 87		Prot No.: 87-36		Status: Ongoing	
Title: A correlational Study of the MCMI, the MMPI, and the Physician's Psychiatric Diagnosis.					
Start Date: May 87			Est Comp Date: Dec 87		
Principal Investigator(s) Sharron K. Schreiber, CPT, MS			Facility: Eisenhower Army Medical Center		
Dept/Svc: Psychiatry			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To analyze the relationship between two personality inventories and the physician's psychiatric diagnosis on an inpatient psychiatric ward in a military hospital.

Technical Approach: The study design is a 3 X 3 factorial design using the three most frequently given psychiatric diagnosis, and the three scales on the MCMI and the MMPI which relate most closely to the diagnosis. Data will be grouped and analyzed with correlational statistics. Approximately 120 records will be reviewed. Diagnoses which will be studied are alcohol abuse, schizophrenia and depression.

Progress: Retrospective review of records is in progress. Amendment to add subjects to the study has been approved, and this portion of the study will begin soon.

# Detail Summary Sheet

Date: 6 Oct 87	Prot No.: 87-37	Status: Terminated
Title: An Evaluation of the Effects of Cognitive Behavioral Training in Enhancing Performance on the Army Physical Fitness Test.		
Start Date: May 87	Est Comp Date: Sep 87	
Principal Investigator(s) Harold C. Dickens, CPT, MS	Facility: Eisenhower Army Medical Center	
Dept/Svc: Psychiatry	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
Study Objective: To investigate the effects of cognitive behavioral interventions as a way to enhance physical performance and increase self-confidence.		

Technical Approach:

Progress: Investigator did not have time to fully implement study before PCS.

# Detail Summary Sheet

Date: 1 Oct 87	Prot No.: 87-44	Status: Ongoing
Title: The Relationship Between Coping Resources and Utilization of Medical Services by Military Personnel		
Start Date: Oct 87	Est Comp Date: Dec 87	
Principal Investigator(s) Martin L. Seitz, CPT, MS	Facility: Eisenhower Army Medical Center	
Dept/Svc: Psychology	Associate Investigators:	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To determine the ability of the Coping Resources Inventory for Stress (CRIS) to discriminate between high and low users of medical services by active duty personnel.

Technical Approach: Administer three inventories and use this data to predict group membership in high/low users of medical services groups, and normal and abnormal illness behavior groups with use of discrete and linear discriminate analysis.

Number of subjects enrolled to date: 0

Progress: Have just received approval from Georgia State University to pursue project. Currently in the process of copying materials to be used. Plan to start data collection on 5 Oct 87.

# Detail Summary Sheet

Date: 23 Sep 87      Prot No.: 87-45      Status: Ongoing  
 Title: Child Psychiatric Data Base Project

Start Date: Jul 87	Est Comp Date: Jul 89
Principal Investigator(s) Peter S. Jensen, MD, MAJ, MC Stephen N. Xenakis, MD, COL, MC Alan M. Josephson, MD Perry L. Wolf, MAJ, MS	Facility:  Eisenhower Army Medical Center
Dept/Svc:  Psychiatry & Neurology, Social Work Svc	Associate Investigators: Don O'Brien, LTC, MS Ms Marilyn Reedy
Key Words:	Earl Loomis, MD, MCG Alex Mabe, PhD, MCG Robert C. Ness, PhD, MCG Harry Davis, M.S., MCG R. Adair Blackwood, MD, Charter Hosp Joseph Frey, PhD, MCG
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To facilitate the development of a collaborative data base and computer scoring system of data items completed by parents or the child's main caretaking figures.

Technical Approach: The 94-item data instrument is presently in use in our routine child psychiatric evaluative settings. Funding requests for a computerized scanner and computerized forms have been initiated.

Progress: Three local hospitals are presently making arrangements to implement the data base into their routine evaluation and treatment settings. No problems or adverse reactions encountered.

# Detail Summary Sheet

Date: 1 Oct 87      Prot No.: 87-50      Status: Ongoing  
 Title: Maternal Olfactory Recognition of Infants

Start Date: Sep 87	Est Comp Date: Jun 88
Principal Investigator(s) Donald W. Grogan, MD, MAJ, MC Peter S. Jensen, MD, MAJ, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Child, Adolescent and Family Psychiatry	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:      Periodic Review Results

Study Objective: To assess the ability of mothers of newborn infants to recognize their own infants by smell.

Technical Approach: Four infants will be held approximately three to five inches from the mothers' noses, one after the other in random sequence. Each mother will be asked to identify which infant is hers on the basis of smell alone. The results will be analyzed statistically to ascertain if the mothers are able to differentially identify their own infant and to correlate the length of prior exposure with the ability to recognize their own infant.

Progress: Study approved in September. No reportable data is available.

# Detail Summary Sheet

Date: 16 Oct 87      Prot No.: 87-29      Status: Ongoing  
 Title: The Effect of Oral Hydration on Bone-to-Soft Tissue Ratios and Subjective Scan Interpretation in Tc 99m Medronate Bone Scans.

Start Date: Mar 87		Est Comp Date:
Principal Investigator(s) Brian Demby, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Radiology/Nuclear Medicine Service		Associate Investigators: James A. Green, SGT, CNMT James H. Algeo, Jr., MD, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To examine the effect of drinking a volume of water after injection for a bone scan and the benefit this might have on the quality of the subsequent images.

Technical Approach: The experiment group will be hydrated 15 minutes following the injection of the radioisotope tracer with one liter of normal tap water under the observation of the medical staff. The water will be ingested over a 45-minute interval. The amount ingested will be recorded for those unable to complete the full amount. The control group will be given the standard instructions to hydrate themselves ad lib. Both experiment and control groups will be scanned approximately four hours following the radioisotope injection.

Number of subjects enrolled to date: 0

Progress: Study not yet implemented due to time constraints.

# Detail Summary Sheet

Date: 1 Oct 87      Prot No.: 78-14      Status: Ongoing  
 Title: Intraocular Lens Study.

Start Date: May 78	Est Comp Date:
Principal Investigator(s) Ophelia Patterson, MD, MAJ, MC Keith C. Moses, MD, CPT, MC	Facility:  Eisenhower Army Medical Center
Dept/Svc: Surgery/Ophthalmology	Associate Investigators:
Key Words: Intraocular Lens      Implant      Ophthalmology Aphakia      Surgery	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Mar 87 Review Results Continue
Study Objective: Implantation of intraocular lenses in accordance with previously established FDA protocol.	

Technical Approach: Currently accepted surgical techniques for cataract extraction and intraocular lens implantation using the operating microscope.

Number of subjects enrolled to date: 796  
 Number of subjects enrolled for reporting period: 113

Progress: During this study period, none of the implanted intraocular lens have been replaced and no adverse effects have been encountered.

# Detail Summary Sheet

Date: 1 Oct 87      Prot No.: 81-18      Status: Ongoing  
 Title: Environmental Stress and Electromyographic Correlates of Chronic Posterior Trunk Muscle Pain.

Start Date: Feb 81		Est Comp Date:
Principal Investigator(s) Kenneth A. Pettine, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation Psychology, Orthopedics		Associate Investigators: Roberto Barja, MD, COL, MC
Key Words: Low back pain Upper back pain Muscle tension		
Accumulative MEDCASE Cost: \$19,000	Est Accumulative OMA Cost:	Periodic Mar 87 Review Results Continue

Study Objective: To record those muscles in the posterior trunk of patients with lower and upper back, shoulder, or neck pain related to abnormal muscle tension in order to ascertain relationships between stress, pain, and tension as well as evaluate the effectiveness of muscular relaxation training as a treatment for these problems. The relative effectiveness of these treatments for pain in the above areas with and without underlying muscle tension problems will be evaluated.

Technical Approach: Recordings of muscle tension; objective psychosomatic measures of stress, anxiety, functional locus and other factors; discomfort logs; and other measures will be made before, during and after muscle relaxation treatments of individuals with the problems described above. These progressive measures will be compared with identical measures made of individuals with: 1) musculoskeletal related pain in other areas; 2) high anxiety but no musculoskeletal pain; and 3) posterior trunk pain but no muscle tension problem. A second phase of the study will consist of continuous muscle tension recordings made throughout the day using wearable EMG recorders. These measures will be related to a continuously tape recorded log of environmental loci and stresses.

Number of subjects enrolled to date: 301  
 Number of subjects enrolled for reporting period: 15

Progress: Study continuing under direction of the Orthopedic Service.

# Detail Summary Sheet

Date: 1 Oct 87		Prot No.: 83-24		Status: Ongoing	
Title: Assessment of Vertical Banded Gastropasty in Treatment of Morbid Obesity.					
Start Date: Apr 83			Est Comp Date:		
Principal Investigator(s) Ross S. Davies, M.D., COL, MC Robert Chadband, M.D., MAJ, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Surgery Medicine Psychiatry and Neurology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Mar 87 Review Results Continue	

Study Objective: To determine if vertical banded stapling is an effective treatment modality for morbid obesity, to determine its long term effectiveness and complications, and to determine if it will prevent the detrimental effects of morbid obesity.

Technical Approach: Weight loss post bypass will be studied in each patient and compared to average weight loss from other centers following the same procedure. Psychologic testing post-operative will be compared to pre-operative results to examine patient self-image pre and post weight loss.

Subjects enrolled to date: 140

Subjects enrolled for reporting period: 25

Progress: Study is ongoing. Weight loss has been completely satisfactory and parallels reported series. In entire group of patients there has been one death (mortality <1%). No significant morbidity has been reported.

# Detail Summary Sheet

Date: 1 Oct 87 Prot No.: 83-27 Status: Ongoing  
 Title: Microsurgery Skill Lab.

Start Date: Nov 83	Est Comp Date:
Principal Investigator(s) Robert Anderson, MD, MAJ, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedic	Associate Investigators: Orthopedic Residents
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Sep 87 Review Results Continue
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Study Objective: In depth exposure to the principles and techniques of microsurgery in a laboratory setting - skills developed being transferable to clinical setting - may also stimulate interest in further research related to field of microsurgery.

Technical Approach: Monthly orthopedic rotation in microvascular surgery for residents with special emphasis on microvascular repair of rat femoral arteries. Surgical application: suture of very small vessels and nerves. The project is being done in periods of 30 to 60 days by one resident and one staff.

Progress: Two senior residents performed the required microsurgery training.

# Detail Summary Sheet

Date: 6 Oct 87		Prot No.: 84-25		Status: Ongoing	
Title: Comparison of Thermography and Standard Techniques for Detection, Diagnosis and Tracing of Peripheral Vascular Disease and Disorders Marked by Altered Patterns of Peripheral Blood Flow.					
Start Date: Mar 84			Est Comp Date:		
Principal Investigator(s)			Facility:		
Roberto H. Barja, MD, COL, MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Surgery/Orthopedics			Robert Anderson, MD, LTC, MC		
Clinical Investigation			Larry Walker, MD, CPT, MC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the optimal utilization of thermography in clinical evaluation of the vascular status of the affected area. This phase of the project is concentrating on correlating near surface blood flow patterns with reports of pain having varied diagnostic etiologies. The aim is to determine whether thermography is a more sensitive and objective method for initially diagnostic and subsequently tracking pain problems with vascular components than current methods.

Technical Approach: Subjects are recorded thermographically as soon as a patient meeting the eligibility criteria requests treatment. This forms a part of the regular work-up for diagnosis of pain in the Orthopedic Clinic. A series of recordings are made as the patient progresses through treatment and follow-up. The results are then compared with the results of the standard clinical evaluation.

Number of subjects enrolled to date: 329

Number of subjects enrolled for reporting period: 100

Progress: With the above numbers we will be in a position to draw final results and get ready for publication

# Detail Summary Sheet

Date: 1 Oct 87 Prot No.: 84-45 Status: Terminated  
Title: Endoscopic Training Lab.

Start Date: Apr 84		Est Comp Date:
Principal Investigator(s) Richard M. Satava, M.D., COL, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Entry level acquaintance with endoscopic skills. The performance of both diagnostic and therapeutic endoscopy on laboratory animals (dogs) in order to develop clinical skills in endoscopy. Also, creation of clinical gastrointestinal entities (pathology, surgical procedures) which can be studied endoscopically for the purpose of training and research.

Technical Approach: There are currently 8 animal models which are maintained on an ongoing basis for endoscopic training of surgical residents and available for training residents from other DDEAMC residency programs on an ad hoc basis. Animal models include: Nissen fundoplication, gastric polyps, antrectomy with Bilioth 1 gastroenterostomy, subtotal gastric resection with Bilioth 2 gastroenterostomy, vertical banded gastroplasty, cholecystoduodenostomy, gastroenterostomy, right hemicolectomy, colectomy with ileo-anal anastomosis. These animals have been maintained in excellent health throughout FY 87.

Progress: Twelve residents were trained on these animals during this reporting period. Investigator has transferred, terminate study.

# Detail Summary Sheet

Date: 15 Sep 87      Prot No.: 85-5      Status: Ongoing  
 Title: Advanced Trauma Life Support Course.

Start Date: Jan 85	Est Comp Date:
Principal Investigator(s) Robert Brigham, LTC, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery Clinical Investigation	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Sep 87 Review Results Continue

Study Objective: To provide training for physicians who are not dealing with major trauma on a day-to-day basis, and who may have to evaluate the seriously injured patient during the period immediately after injury. Also, it is intended to provide the basic knowledge and skills necessary to identify those patients whose need is for rapid assessment, resuscitation, and stabilization.

## Technical Approach:

a. Design: The Advanced Trauma Life Support Course is a two day training session in which participants are given didactic instruction followed by practical skill stations and an animal lab. Testing is accomplished by a written exam and a practical exercise in which a simulated trauma victim is resuscitated.

b. Manpower: Requirements are as follows:

- Course Director (1 MC)
- Course Administrator (MS)
- Instructors (6 MC)
- Logistical Support (2 EM)
- Moulage patients (4 EM)

c. Funding: Administrative cost derived from Office of Medical Education.

Progress: During the past year one Advanced Trauma Life Support Instructor Course was conducted (8-10 October 1986). This was very successful with the training of 16 new instructors. The animal lab portion of the course proceeded efficiently and was extremely helpful in the training of our students.

# Detail Summary Sheet

Date: 15 Sep 87 Prot No.: 85-15 Status: Terminate  
 Title: The Treatment of Segmental Bone Loss in Rabbit Femora with Alveograf<sup>R</sup>.

Start Date:	Est Comp Date:
Principal Investigator(s) Larry T. Donovan, CPT, MC J. Allan Goodrich, MAJ, MC	Facility:  Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedic Surgery	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To determine if union can be achieved after segmental resection of bone from rabbit femora using a non-resorbable ceramic bone grafting implant as a scaffold for bone ingrowth with and without supplemental autogenous bone graft from the animal's iliac crest.

Technical Approach: Rabbits will undergo segmental resection of 10% and 20% of the femoral diaphysis to simulate traumatic loss of bone. These defects will be replaced by Alveograf, a non-resorbable ceramic bone grafting implant material.

Progress: Terminate due to PCS of both investigators.

# Detail Summary Sheet

Date: 3 Aug 87      Prot No.: 85-36      Status: Completed  
 Title: Implantable Artificial Anal Sphincter (Swine) (Phase II).

Start Date: Nov 85	Est Comp Date:
Principal Investigator(s) Richard M. Satava, LTC, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery Clinical Investigation	Associate Investigators: Michael P. Byrne, MAJ, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: Phase II will focus on developing the technique of implanting the sphincter in the pelvis, and overcoming the minor technical complications associated with intraabdominal implantation. In addition, by using a commercially available valve and reservoir, the entire sphincter mechanism will be investigated as a totally implantable system.

Progress: Completed.

# Detail Summary Sheet

Date: 6 Oct 87      Prot No.: 86-8      Status: Ongoing  
 Title: Ultrasound Evaluation of the Rotator Cuff.

Start Date: Feb 86	Est Comp Date:
Principal Investigator(s) Roberto H. Barja, COL, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Orthopedic	Associate Investigators: Michael J. Quinn, MAJ, MC Robert C. Anderson, MAJ, MC Michael Drakeford, CPT, MC Stephen L. Simpson, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: Attempt to determine the sensitivity and specificity of ultrasound in diagnosing rotator cuff tears and pathology.

Technical Approach: The experimental design is to compare the diagnostic value of blind noninvasive ultrasound with subsequent arthrogram and arthroscopy in shoulders with symptomatic rotator cuff disease. Additionally, the blind ultrasound studies of the symptomatic shoulders will be compared with the blind ultrasound studies of 50 clinically asymptomatic shoulders in individuals 18-35 years of age.

Manpower involves one radiologist who will do all of the ultrasound studies and four orthopedists who will accomplish the examinations and referrals.

No specific funding has been required.

Number of subjects enrolled to date: 54

Number of subjects enrolled for reporting period: 40

No adverse reactions noted.

Progress: With the above numbers we will be in a position to draw final results and get ready for publication.

# Detail Summary Sheet

Date: 3 Aug 87		Prot No.: 86-11		Status: Completed	
Title: Omental Splenic Autotransplantation: Optimal Transplant Size for Maximal Protective Effect Against Pneumococcal Bacteremia.					
Start Date: Jan 86			Est Comp Date:		
Principal Investigator(s) Richard M. Satava, LTC, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Surgery, Clinical Investigation			Associate Investigators:		
Key Words: Splenectomy, Autotransplantation					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To compare five quantities of splenic tissue autotransplantation in order to establish the optimal splenic transplant for the maximal protective effect against a challenge of Streptococcus pneumoniae.

Technical Approach: Rats were divided into seven groups: control, total, splenectomy, 25%, 40%, 60%, 80% and 100% omental pouch autotransplantation. These animals were challenged with intravenous S. pneumoniae type 1 after 24 weeks and mortality and blood culture results monitored. Transplants were recovered and weights compared with the weights originally transplanted.

Progress: Survival and blood culture results were seen to improve in a linear quantitative fashion as the amount of spleen autotransplanted increased up to 80%, after which no further improvement was seen. This data supports the autotransplantation of 80% of the spleen in the Sprague-Dawley rat as the optimum amount to achieve maximal survival in a model of pneumococcal sepsis.

# Detail Summary Sheet

Date: 20 Jul 87 Prot No.: 86-13 Status: Terminated  
 Title: The Effects of Pentoxifylline (Trental) on Vasculogenic Impotence.

Start Date: Jun 86	Est Comp Date:
Principal Investigator(s) James B. Rounder, M.D., CPT, MC	Facility:
Dept/Svc: Surgery/Urology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost: Periodic Jul 87 Review Results Terminated

Study Objective: To determine if Pentoxifylline, an agent that has been shown to improve capillary blood flow, will improve vasculogenic erectile impotence.

Technical Approach: Experimental design - Fifty male subjects with fasculo-genic impotence will be randomized in a double-blind trial to evaluate Pentoxifylline (Trental) as a treatment modality. Data will be evaluated on the basis of subjective improvement in impotence as well as objective changes in penile doppler studies.

Manpower - Urology and Vascular Surgery Service.  
 Vascular Lab Technicians.  
 Pharmacy

Funding - From existing Pharmacy supplies of Trental and placebo (multi-vitamin): about \$4,000.

Number of subjects enrolled to date: 3  
 Number of subjects enrolled for reporting period: 0

No significant adverse reactions.

Progress: Investigator requested termination of study; unable to accrue additional subjects.

# Detail Summary Sheet

Date: 23 Sep 87		Prot No.: 87-5		Status: Terminated	
Title: A Comparison of Sympathetic Block Versus Placebo Prevention of Post Herpetic Neuralgia.					
Start Date:			Est Comp Date:		
Principal Investigator(s) G. Lee Brookshire, MD, MAJ, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Surgery/Anesthesia & Operative Service			Associate Investigators: Marshal A. Guill, MD, LTC, MC		
Key Words:			John Cook, MD, COL, MC		
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: To test the effectiveness of sympathetic block versus placebo in the prevention of post herpetic neuralgia.					

Technical Approach:

Number of subjects enrolled for reporting period: 0

Progress: Study was not initiated due to lack of patients.

# Detail Summary Sheet

Date: 15 Sep 87		Prot No.: 87-6		Status: Ongoing	
Title: Postoperative Analgesia After the Addition of Morphine or Hydramorphone to Intrathecal Tetracaine for Total Joint Surgery.					
Start Date: Dec 86			Est Comp Date: Nov 87		
Principal Investigator(s) G. Lee Brookshire, MD, MAJ, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Surgery/Anesthesia & Operative Service			Associate Investigators: Thomas W. Overly, CPT, AN Frank R. Ebert, MAJ, MC Kenneth A. Pettine, CPT, MC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine if intrathecal opiates provide for better postoperative pain relief and hence shorter hospitalization, fewer complication rates, and better orthopedic outcomes.

Technical Approach: Patients will be enrolled into one of three groups. The first group will receive the usual spinal anesthetic with tetracaine and receive IV and IM narcotics postoperatively. The second group will receive the tetracaine spinal anesthetic with dilaudid added. Their postoperative pain will also be managed with IV and IM narcotics. The third group will receive the usual tetracaine spinal anesthetic with duramorph added. Again, their postoperative pain will be managed by IV and IM narcotics. All patients will then spend the first postoperative day in the SICU. Once they are stable, patients will spend the remainder of their hospitalization on the ward.

Number of subjects enrolled to date: 59

Progress: Data being gathered and collated now and will begin to analyze the data by mid October. Plan is to submit this for publication by the end of 1987.

# Detail Summary Sheet

Date: 15 Sep 87      Prot No.: 87-8      Status: Ongoing  
 Title: Serum Creatine Kinase and the Acute Abdomen.

Start Date:	Est Comp Date:
Principal Investigator(s) William M. Steely, MD, CPT, MC	Facility: Eisenhower Army Medical Center
Dept/Svc: Clinical Investigation	Associate Investigators: Robert A. Brigham, MD, LTC, MC Ross S. Davies, MD, COL, MC James Hancock, MD, CPT, MC
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To analyze a series of patients with acute surgical abdomens and correlate the findings at operation with preoperative creatine kinase serum isoenzyme levels. To determine if such correlation may provide additional presumptive diagnostic information as to the viability of the bowel. To examine the relationship in ratio of lactate dehydrogenase (LDH) isoenzymes and creatine (CK) isoenzymes during the same preoperative period in individuals with mesenteric infarction, bowel obstruction and other acute surgical emergencies.

Technical Approach: Patients will have their blood drawn as part of the normal preoperative laboratory evaluation and again 24 hours postoperatively. The patients' blood will be analyzed for the total creatine kinase (CK), percent of each CK isoenzyme, total lactate dehydrogenase (LD), and percent of each LD isoenzyme.

Number of subjects enrolled to date: 6

Progress: Data is currently being collected for this protocol. Prior to his departure, Dr. Steely had collected lab results on six patients. None of these patients had compromised bowel. Further data is being collected.

# Detail Summary Sheet

Date: 23 Sep 87      Prot No.: 87-9      Status: Ongoing  
 Title: Iontophoresis of Steroids: Does it Affect Rabbit Tendon Strength.

Start Date: May 87		Est Comp Date:
Principal Investigator(s) Paul J. Herzwurm, MD, CPT, MC		Facility: Eisenhower Army Medical Center
Dept/Svc: Surgery/Clinical Investigation		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To study the effect of iontophoresis of steroids on rabbit tendon strength.

Technical Approach: The study was performed last May but we ran into technical difficulties in clamping the tendons when testing their tensile strength.

Progress: I am communicating with Dr. Svendron in Denmark about the clamps he has designed for clamping tendons, and also with zimmer pharmaceuticals about their clamps. Will plan to do the experiment again this year.

# Detail Summary Sheet

Date: 23 Sep 87	Prot No.: 87-11	Status: Terminated
Title: Evaluation of the Garren-Edwards Gastric Bubble - A Controlled Clinical Trial.		
Start Date:	Est Comp Date:	
Principal Investigator(s)	Facility:	
Richard M. Satava, MD, COL, MC	Eisenhower Army Medical Center	
Dept/Svc:	Associate Investigators:	
Surgery		
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
Study Objective:		

Technical Approach:

Number of subjects enrolled to date: 0

Progress: This protocol was never initiated because it was decided that the recently published literature as well as information from others at meetings adequately answered all questions concerning this matter.

# Detail Summary Sheet

Date: 3 Aug 87		Prot No.: 87-12		Status: Completed	
Title: Development of Surgical Techniques in the Simulated Space Environment Using Neutral Buoyancy.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Richard M. Satava, MD, COL MC			Eisenhower Army Medical Center		
Dept/Svc:			Associate Investigators:		
Surgery, Clinical Investigation					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To create a working model which will simulate the space environment and allow for investigation of the peculiarities of this milieu. To modify or create new surgical instruments to work under these unusual conditions. To identify specific technical problems, validate their uniqueness, propose solutions, and ultimately perform surgical procedures with competence.

Technical Approach:

Progress: Completed.

# Detail Summary Sheet

Date: 1 Oct 87	Prot No.: 87-13	Status: Ongoing
Title: Enhancement Video Endoscopy: Preliminary Assessment of Digital Enhancement.		
Start Date:	Est Comp Date:	
Principal Investigator(s)	Facility:	
Stephen M. Gooden, MD, LTC, MC	Eisenhower Army Medical Center	
Dept/Svc:	Associate Investigators:	
Surgery, Clinical Investigation	Roosevelt J. Stallings, MD, LTC, MC	
Key Words:	Albert B. Baffoni, MD, MAJ, MC	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To perform initial assessment of various methods of enhancing and electronically analyzing video images of the gastrointestinal tract in both normal dogs and dogs with surgically created pathology,

Technical Approach: The experiment is designed to perform standard video endoscopic procedures and to enhance the image either directly during the procedure or later from the video tape recording utilizing various methods of computer and video electronic image processing.

Progress: Equipment has just arrived and is currently being installed.

# Detail Summary Sheet

Date: 1 Oct 87	Prot No.: 87-30	Status: Ongoing
Title: A Comparison of Labetalol and Sodium Nitroprusside in Postoperative Patients Undergoing Carotid Endarterectomy.		
Start Date: Mar 87	Est Comp Date: Mar 88	
Principal Investigator(s) Daniel J. Geniton, CRNA, CPT, AN	Facility: Eisenhower Army Medical Center	
Dept/Svc: Surgery/Anesthesia & Operative Service	Associate Investigators: G. Lee Brookshire, MD, MAJ, MC	
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
Study Objective: To assess if labetalol is as effective as nitroprusside in controlling postoperative hypertension in carotid endarterectomy.		

Technical Approach: Subjects are randomized into two groups, given a standard anesthetic protocol, and are given either labetalol or nipride when they achieve a target blood pressure. Data (systolic, diastolic, and mean BP) is then recorded for 12 hours while the subject is in SICU. There are no funding or manpower considerations at this point. There have been no adverse reactions to treatment in any subject to date.

Number of subjects enrolled to date: 12

Progress: The study continues with 12 subjects completed to date. The target is 30 subjects before completion. Data has not been analyzed yet, so no tentative conclusions can be drawn; it appears that labetalol is as effective (subjectively) as nipride in managing blood pressure following CEA. We will continue to gather data to test this impression.

# Detail Summary Sheet

Date: 1 Oct 87		Prot No.: 87-35		Status: Ongoing	
Title: Omental Splenic Autotransplantation: Optimal Transplant Size for Maximal Protective Effect Against Pneumococcal Bacteremia.					
Start Date: Mar 87			Est Comp Date:		
Principal Investigator(s) Edward McWhirt, MD, CPT, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Surgery/Clinical Investigation			Associate Investigators: Edward R. Setser, MD, CPT, MC Robert A. Brigham, MD, LTC, MC Ross S. Davies, MD, COL, MC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To compare five quantities of splenic tissue autotransplantation in order to establish the optimal splenic transplant for the maximal protective effect against a challenge of *Streptococcus pneumoniae* using LD-50 determinations for each percentage group of the experimental animals.

Technical Approach: After its removal, the spleen will be diced into small 1mm x 2mm x 2mm pieces. Autotransplantation will consist of 20%, 40%, 60%, 80% and 100% of the spleen transplanted in an omental pocket. A culture of *Streptococcus pneumoniae* type I will be used for inoculation. Organisms will be passed through a rat multiple times to ensure encapsulation prior to challenge. Serotype will be confirmed by type I specific antisera and india ink preparations will be used to check for the presence of a capsule.

Progress: 350 of 450 animals have had autotransplantation of the spleen. They are currently within one month of the four months required for maturation of transplant. At four months animals will be challenged and sacrificed at 48 hours.

# Detail Summary Sheet

Date: 1 Oct 87		Prot No.: 87-47		Status: Ongoing	
Title: Evaluation of Plasma Catecholamines in Patients Undergoing General Anesthesia for Surgical Procedures					
Start Date: Sep 87			Est Comp Date: Nov 87		
Principal Investigator(s) Alan S. Black, MD, CPT, MC G. Lee Brookshire, MD, MAJ, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Surgery/Anesthesiology & Operative Svc			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To evaluate the role of epinephrine on memory and learning during anesthesia.

Technical Approach: Blood will be drawn for plasma catecholamine assay immediately prior to induction, immediately after induction, post-intubation, post surgical skin incision, then every half hour until the conclusion of the case.

Progress: Study approved late September, no available data.

# Detail Summary Sheet

Date: 1 Oct 87		Prot No.: 87-52		Status: Ongoing	
Title: The Richards II Series Total Hip Prosthesis: A Clinical Review with a Minimum 2-year Follow-up Evaluation					
Start Date: Oct 87			Est Comp Date: May 88		
Principal Investigator(s) David A. Volgas, CPT, MC			Facility: Eisenhower Army Medical Center		
Dept/Svc: Surgery/Orthopedic Service			Associate Investigators: Frank C. Ebert, MAJ, MC		
Key Words:			Harvey Montijo, CPT, MC Roberto H. Barja, COL, MC		
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the long-term (2 years or greater) clinical failure rate of the Richards Series II total hip prosthesis.

Technical Approach: The study will include a chart review and a routine follow-up physical and radiographic examination by one of the investigators as well as a patient questionnaire.

Progress: Study approved in September. No reportable data available.

# Detail Summary Sheet

Date: 1 Oct 87		Prot No.: 87-54		Status: Ongoing	
Title: The Effect of Position and Supplemental Oxygen on Arterial Oxygen Saturation During Transport to the Post-Anesthesia Care Unit					
Start Date: Oct 87			Est Comp Date: Jan 88		
Principal Investigator(s) Daniel J. Geniton, CPT, AN			Facility: Eisenhower Army Medical Center		
Dept/Svc: Surgery/Anesthesia & Operative Service			Associate Investigators: G. Lee Brookshire, MD, MAJ, MC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine the effect of three transport positions on arterial oxygen saturation during transport to post-anesthesia care unit and to examine the effect of providing supplemental oxygen to patients during transport to post-anesthesia care unit.

Technical Approach: Subjects will be randomized into one of six groups and have pulse oximetric determination of SaO<sub>2</sub> recorded.

Progress: Study approved in September, not yet implemented.

# Detail Summary Sheet

Date: 1 Oct 87		Prot No.: 87-55		Status: Ongoing	
Title: An Evaluation of the Effects of Hearing Protective Devices on Speech Recognition Performance in Noise of Hearing-Impaired Listeners					
Start Date: Oct 87			Est Comp Date: May 88		
Principal Investigator(s) Graham L. Wilde, MAJ, MS			Facility: Eisenhower Army Medical Center		
Dept/Svc: Surgery/Audiology			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To investigate the effects of hearing protection on speech recognition performance of listeners with mild to moderate high frequency, noise induced hearing loss.

Technical Approach: Subjects will be tested without hearing protection and while wearing each of the hearing protectors in a background of speech-shaped noise. The speech noise is similar in spectral shape to the competing noises commonly found in everyday situations. The test material will consist of test items from the revised Speech Perception In Noise (SPIN) test.

Progress: Study approved in September, not yet implemented.

# Detail Summary Sheet

Date: 13 Oct 87      Prot No.: 78-14      Status: Ongoing  
 Title: Intraocular Lens Study.

Start Date: Nov 80	Est Comp Date:
Principal Investigator(s) William C. Lloyd, MD, MAJ, MC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Surgery/Ophthalmology	Associate Investigators: Mary A. O'Hara, MD, MAJ, MC
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 87 Review Results Continue
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Study Objective: Provide data to support FDA approval for marketing intraocular devices.

Technical Approach: Surgical insertion of intraocular lens. Presently, intraocular lenses selected for implantation include IOLAD Model G108B, 3M Vision Care Style 83, Precision-Cosmet Model 8201, and Cilco Styles SK21V0, SAC5V0.

Number of subjects enrolled to date: 470  
 Number of subjects enrolled for reporting period: 48

Progress: All lenses are FDA approved; case registration performed as part of adjunct safety study.

# Detail Summary Sheet

Date: 13 Oct 87		Prot No.: 85-34		Status: Terminated	
Title: Adolescent Medicine: Attitudes and Skills of Internal Medicine, Pediatric and Family Practice Residents.					
Start Date: Oct 85			Est Comp Date: Jan 1986		
Principal Investigator(s) Thomas Goodell, CPT, MC			Facility: USA MEDDAC, Fort Benning, GA		
Dept/Svc: Family Practice			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: This study is an attempt to identify the expectations to provide care and the patient care skills of residents from Internal Medicine, Pediatrics and Family Practice.

Technical Approach: The study consists of a one-time survey evaluating desire and expectations to care for certain age groups, perceived ability to care for certain health problems within these age groups and perceived need for certain patient care skills and their ability at these same skills. The subject population consists of all Internal Medicine, Pediatric and Family Practice residents in US Army training programs.

Number of subjects enrolled to date: 40-50 in each study group.  
Number of subjects enrolled for reporting period: 0

Progress: Data (survey forms) have been collected. It has been impossible to process the data due to lack of statistical and data processing support. Therefore, project is terminated due to support difficulties as noted above.

# Detail Summary Sheet

Date: 13 Oct 87		Prot No.: 86-1		Status: Terminated	
Title: A Phenomenological Study of Patients Receiving Initial Chemotherapy for Carcinoma of the Lung.					
Start Date: Oct 85			Est Comp Date: Jun 87		
Principal Investigator(s) Nancy Penaskovic			Facility: USA MEDDAC, Ft Benning, GA		
Dept/Svc: Auburn University			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: The purpose of this study is to explore the patients' experience while receiving chemotherapy in order to:

- a. Develop a more thorough knowledge base to understand how chemotherapy affects patients;
- b. analyze the data to generate implications for improvement in the quality of care given to chemotherapy patients;
- c. develop a conceptual analysis of the perceptive world of patients receiving chemotherapy; and
- d. to suggest avenues for further research.

Technical Approach: Four male subjects with a known diagnosis of carcinoma of the lung between the ages of 45-78 will be selected in conjunction with the treating physician and will be interviewed before their therapy is begun, during the course of their chemotherapy, and at subsequent follow-up visits at the physician's office. The interaction with the patient will be taped with permission of the subject.

Number of subjects enrolled to date: 2

Number of subjects enrolled for reporting period: 0

Progress: This study is terminated because of the inability to contact the principal investigator. She is no longer collecting data at Fort Benning.

# Detail Summary Sheet

Date: 13 Oct 87      Prot No.: 86-18      Status: Completed  
 Title: Efficacy of Postpartum Uterine Exploration and Curretage.

Start Date: Apr 86	Est Comp Date: May 1987
Principal Investigator(s) Ted D. Epperly CPT, MC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice	Associate Investigators: John P. Fogarty, MD, LTC, MC
Key Words: Postpartum, Exploration, Curretage	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:      Periodic Review Results

Study Objective: The study objective is to determine if it is necessary to explore and/or curretage postpartum uterine in uncomplicated vaginal deliveries.

Technical Approach: A questionnaire to be filled out by both nurse and physician will be placed in the charts of all vaginal deliveries done at Martin Army Community Hospital. The principal investigator and postpartum nurses will then follow-up all vaginally delivered patients for a period of 10 days to establish the incidence of postpartum hemorrhage and endometritis. Assessment of these entities will be done by means of attached data sheet, CBC, temperatures, antibiotics, and blood administration. Endometritis will be assessed by means of the fever index and bleeding by means of hematocrits and the lochia scale. Additionally, all women who underwent exploration and/or curretage will be given a questionnaire about this procedure prior to discharge.

Number of subjects enrolled to date: 321  
 Number of subjects enrolled for reporting period: 231

Progress: The study was completed on 15 May 1987. A total of 321 patients were enrolled. Data is now being computerized and analyzed. Project in its written form should be completed by 1 December 1987.

# Detail Summary Sheet

Date: 13 Oct 87 Prot No.: 86-19 Status: Completed  
 Title: Health Risk Appraisal of Early Adolescents.

Start Date: Jan 86		Est Comp Date:
Principal Investigator(s) Wayne G. Stanley, MAJ, MC		Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
Study Objective: To identify the areas of increased biophysical and behavioral health risks in the study population.		

Technical Approach: A two component Health Risk Appraisal questionnaire will be administered to eighth grade students at Faith School and ninth grade students at Spencer High School.

Number of subjects enrolled to date: 540  
 Number of subjects enrolled for reporting period:

Progress: This study as been completed. The principal investigator PCS'd, therefore a final report is not available.

# Detail Summary Sheet

Date: 13 Oct 87		Prot No.: 86-26		Status: Ongoing	
Title: A Randomized, Controlled Trial of Initially Treated Corneal Abrasions: Physician Mandated Every 24 Hours Follow-Up Versus Patient Initiated (PRN) Follow-Up.					
Start Date: Jul 86			Est Comp Date:		
Principal Investigator(s) Ted D. Epperly, MD, MAJ, MC			Facility: USAMEDDAC, Ft Benning, GA		
Dept/Svc: Family Practice			Associate Investigators: Mark A. Connelly, MD, CPT, MC Steven E. Reissman, DO, CPT, MC Frank Celestino, MD, Bowman Gray School of Med, Winston Salem, SC		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine if patients need to be checked on a daily basis for healing of their corneal abrasion versus a PRN approach to follow-up if symptoms/signs develop.

Technical Approach: This study will be a randomized, prospective controlled trial involving patients with uncomplicated corneal abrasions. A full eye exam will be done on all patients and all patients will then be treated in a standardized fashion. Patients will then be randomized into two groups for follow-up: Group 1 will receive daily follow-up and reexamination until healing is documented (negative flourescein) and symptoms are gone. Group 2 will be instructed to leave patch on for 36 hours and then remove. Upon patch removal, follow-up will be PRN and patient-initiated based on the patient's perception of persistent bothersome symptoms. Data will be analyzed using the chi-squared methodology for dichotomous variables. The measured outcome variables will be number of re-visits, complications, and days of symptoms in each group.

Number of subjects enrolled to date: 0

Number of subjects enrolled for reporting period: 0

Progress: This project has not yet been started due time demands on the principal investigator. It will be started in January 1988.

# Detail Summary Sheet

Date: 6 Oct 87      Prot No.: 86-27      Status: Ongoing  
 Title: The Effect of the Internship on Fitness

Start Date: Jun 86	Est Comp Date: Jul 88
Principal Investigator(s) John M. Henderson, DO, CPT, MC	Facility: USAMEDDAC, Ft Benning, GA
Dept/Svc: Family Practice	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To assess a change in physiologic parameters during the internship year.

## Technical Approach:

1. Assess several parameters of fitness prior to beginning duty in the PGY-1, prior to 1 July 1986.
2. Reassess these parameters 6 months into the PGY-1, and again 12 months into the PGY-1.
3. Compare each individual's performance against their earlier findings, against their confreres and against an age-matched national mean for the Army and the general civilian population.

Number of subjects enrolled to date: 9

Number of subjects enrolled for reporting period: 0

Progress: Not completed due to lack of data collection. Plan to extend to July 1988 to follow cohort group.

# Detail Summary Sheet

Date: 13 Oct 87		Prot No.: 87-24		Status: Completed	
Title: The Actual Biomechanics of the Parachute Landing Fall and the Proper Conditioning Needed to Minimize Injuries.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
John M. Henderson, MD, MAJ, MC			MEDDAC, Ft Benning, GA		
Dept/Svc:			Associate Investigators:		
Family Practice			W. Jeff Berry, CPT, MC		
Key Words:			Stephen C. Hunter, M.D.		
Accumulative MEDCASE		Est Accumulative		Periodic	
Cost:		OMA Cost:		Review Results	

Study Objective: To document the actual kinematics and EMG of the "novice jumper's" parachute landing fall.

Technical Approach: Using two means of motion study (EMG and Video), we documented the learning process of the decelerator mechanism through Airborne School.

Number of subjects enrolled to date: 48

Progress: The study is complete and ready to be submitted for publication. It has already been presented at The Hughston Sports Medicine Foundation Annual Foreign Fellows Day, Columbus, Georgia; the XIII Scientific Assembly of USAFP, Orlando, Florida; and the Army War College's Fitness of the Army Seminar, Carlisle Barracks, Pennsylvania.

# Detail Summary Sheet

Date: 13 Oct 87      Prot No.: 87-25      Status: Terminated  
 Title: Visual Reaction Time of Competitive Shooters.

Start Date:	Est Comp Date:
Principal Investigator(s) David O. Peed, O.D.	Facility: MEDDAC, Ft Benning, GA
Dept/Svc: Hughston Sports Clinic	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To investigate the relationship between improved visual abilities through orthoptic exercises and increased skill level in experienced marksmen.

Technical Approach: Project Design: Double-blind study with human subjects undergoing training procedures designed to enhance visual skills.  
 Experimental group received valid training, control group received placebo training.

Number of subjects enrolled to date: Initially 13 were enrolled; all have been disenrolled for failure to comply with testing and training schedule due to either: 1) lack of personal motivation, or 2) conflicts with military duties.

Progress: This project has been terminated for the reasons listed above.

# Detail Summary Sheet

Date: 13 Oct 87		Prot No.: 87-26		Status: Completed	
Title: A Descriptive Study of the Self-Esteem of Mothers of Father-Daughter Incest Victims.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Jane E. Jones			MEDDAC, Ft Benning, GA		
Dept/Svc:			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: To measure the self-esteem of mothers whose daughters have been sexually abused by their father or father figure.					

Technical Approach: Available population will be asked to anonymously complete a 25 item index created by Walter W. Hudson to measure the level of self-esteem. When the data are collected, measurements of central tendency will be determined, as will the range of scores and the standard deviation from a simple frequency distribution due to the nonprobability sampling technique and the univariate nature of the study.

Number of subjects enrolled to date: 6  
 Number of subjects enrolled for reporting period: 6

Progress: The study has successfully been completed. Five respondents completed the survey with 4 out of 6 indicating low self-esteem.

# Detail Summary Sheet

Date: 13 Oct 87		Prot No.: 87-41		Status: Ongoing	
Title: An Exploration of the Relationship Between Client Expectations and the Working Alliance					
Start Date: 30 Sep 87			Est Comp Date: Dec 87		
Principal Investigator(s) Scott S. Jones, M.A.			Facility: USAMEDDAC, Ft Benning, GA		
Dept/Svc: Social Work Services/Psychiatry Services			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To measure the shape and strength of the relationship between the expectations about counseling held by individual adult outpatients who are entering counseling for the first time and the working alliance developed between the individuals and their counselors. The study will also examine: 1) which types of expectations best predict the working alliance, 2) whether initial expectations about counseling differ significantly from initial preferences, 3) if such difference exists, whether expectations or preferences best predict the working alliance, and 4) what effect disconfirmation of client expectations or preferences has on the status of working alliance.

Technical Approach: The experimental design of the study is correlational. Subjects are informed of the nature of the study prior to consenting to participate. Subjects fill out questionnaires defining their expectations of counseling before the first counseling session. Following the third counseling session subjects fill out questionnaires defining their relationship with their counselors. Data from the questionnaires are correlated to define the shape and strength of the working or therapeutic reliance.

Manpower: Counselors from Social Work Services, psychiatric Services, and Alcohol and Drug Services are used as counselors for the study.

Number of subjects enrolled to date: None

Progress: No results have been obtained to date.

# Detail Summary Sheet

Date: 13 Oct 87 Prot No.: 87-42 Status: Completed  
 Title: The Epidemiology of Training Injuries in Army Infantry Trainees.

Start Date: Feb 87	Est Comp Date: May 87
Principal Investigator(s) Bruce H. Jones, M.D., MAJ, MC	Facility: USAMEDDAC, Ft Benning, GA
Dept/Svc: USARIEM	Associate Investigators: David Cowan, CPT, MS (WRAIR) J. Pitt Tomlinson, LTC, MC (Ft Benning) Katy Reynolds, MAJ, MC (AHS) Michael Moore, CPT, MC (AHS) David Polly, CPT, MC (WRAIR)
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: The objective of this project is threefold: 1) To identify the magnitude of risk for musculoskeletal injuries in Infantry One Station Unit Training companies at Fort Benning, GA. 2) To identify risk factors for physical training injuries in these training units and the relative importance of different risk factors in the causation of injury. 3) To propose interventions in current selection criteria and training routines for further study and consideration for implementation of Army policy.

Technical Approach: The study was conducted in two phases: Phase 1 took place the week prior to the beginning of training over a period of two days on a weekend. During Phase 1 a questionnaire was delivered to collect demographic data and to assess the level of physical activity and history of injuries for each participant prior to entrance into the Army. Also, during the week before the start of training, anthropometric measures, morphologic characteristics, flexibility, body composition, and muscle strength were assessed on each trainee participating. Phase 2 took place during the course of OSUT training (13 weeks). More objective data was acquired on entry level physical fitness from results of the initial physical training test (2 mile, sit ups, and push ups), data which units routinely collect as part of normal training. During the training cycle, training activities were documented on a daily basis. Footwear was periodically inspected. Also, during this period, adverse outcomes of training, i.e., injuries, discharges, etc., were carefully and systematically documented.

Number of subjects enrolled to date: 320

Progress: The project as described in the original protocol was conducted February through May 1987. Two companies of basic trainees (160 men each) were studied. All observations, chart reviews, and data collection were completed in May 1987. Data is currently being entered into the computer and analysis is not complete. Final results should be available in the next few months. When data has been analysed and results known, MAJ Jones would like to return to Ft Benning to brief both ATC and MEDDAC personnel.

# Detail Summary Sheet

Date: 13 Oct 87		Prot No.: 87-56		Status: Ongoing	
Title: Comparison of Psyllium Plantago and Xanthan Gum in the Dietary Management of Diabetes Mellitus					
Start Date: Sep 87			Est Comp Date: Mar 88		
Principal Investigator(s) John D. Cowsar, DO, MAJ, MC			Facility: USA MEDDAC, Fort Benning, GA		
Dept/Svc: Family Practice Community Medicine			Associate Investigators: Donn Richards, MD, CPT, MC Carol Handley, MAJ, MS		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To demonstrate that feeding psyllium plantago mucilloid and xanthan food gum can effectively improve glucose intolerance in patients with non-insulin dependent diabetes.

Technical Approach: Psyllium plantago mucilloid fiber (12 gm/day) and xanthan good gum (12 gm/day) will be administered for 6 week intervals in a double blind, placebo cross-over design to determine which fiber is more effective in improving glucose tolerance and lowering cholesterol and triglyceride levels. There will be a 3 week washout period between the test periods. Forty-eight adult subjects with non-insulin dependent diabetes mellitus having elevated fasting blood glucose within the range of 150-250 mg/dl will comprise the test group. The test subjects will serve as their own controls. Fasting, 1, and 2 hour post 75 gm oral glucose challenge serum glucose and insulin measurements will be obtained at the start of the study, and at the end of the test and placebo periods. Fasting total cholesterol, HDL fraction, and triglycerides will be measured at the beginning of the study and after 6 weeks of each study period. A questionnaire will be administered to evaluate side effects. A 3 day diet diary will be obtained prior to the study and during each test period to estimate the carbohydrate, protein, fat, and nonabsorbable fiber content. Laboratory results will be analyzed to confirm the presence of a significant clinical effect of these two viscous fiber analogues in terms of their ability to improve glucose tolerance and lower cholesterol and triglyceride levels in an inert placebo. A comparison will also be made between psyllium and xanthan gum to determine if there is a significant difference in their individual efficacy.

Progress: Study approved locally in late FY 87, not yet implemented.

# Detail Summary Sheet

Date: 13 Oct 87      Prot No.: 87-57      Status: Ongoing  
 Title: The Relationship Between Airborne Activities and Knee Pain

Start Date: Sep 87	Est Comp Date:
Principal Investigator(s) John M. Henderson, MD, MAJ, MC	Facility: USA MEDDAC, Fort Benning, GA
Dept/Svc: Family Practice Community Medicine	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results
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Study Objective: The common presentation of anterior knee pain syndromes in airborne soldiers has prompted investigation into the stress placed on the extensor mechanism of the knee from airborne activities versus other non-airborne soldierly activities. This study compares the knee profiles of both airborne and non-airborne soldiers.

Technical Approach: The knee profiles consist of demographic, historical, clinical, and radiographic information that is matched concurrently by age, occupation, time in service, miles run per week, and current sports activities.

Number of subjects enrolled to date: 50 airborne and 50 non-airborne.

Progress: Study approved locally in late FY 87, no reportable data.

# Detail Summary Sheet

Date: 13 Oct 87		Prot No.: 87-58		Status: Ongoing	
Title: Quantifying the Ranger Experience: The Clinical Aspects of Elite Military Training and Over-training					
Start Date: Sep 87			Est Comp Date:		
Principal Investigator(s) John M. Henderson, UO, MAJ, MC			Facility: USA MEDDAC, Ft Benning, GA		
Dept/Svc: Family Practice Community Medicine			Associate Investigators: W. Jefferson Berry, CPT, MC James E. Mace, COL, IN		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To investigate the effect of training, induced changes in anthropometric and physiologic parameters on psychologic affect and general fitness parameters.

Technical Approach: Anthropometric, physiologic, psychologic, and general fitness measurements will be followed through Phase 1 of Ranger School.

Number of subjects enrolled to date: 11

Progress: Data analysis is ongoing. Data collection will be expanded.

# Detail Summary Sheet

Date: 13 Oct 87      Prot No.: 87-59      Status: Ongoing  
 Title: Core Temperatures in Soldiers During Routine Physical Training

Start Date: Sep 87		Est Comp Date: Aug 88
Principal Investigator(s) W. Jeff Berry II, MD, CPT, MC		Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice Community Medicine		Associate Investigators: John M. Henderson, DO, MAJ, MC
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To describe the physiologic response to training in the heat at the Infantry Training Center.

Technical Approach: Phase one is a prospective description of a pilot nature for Phase two. During this phase the wet bulb globe temperature index and associated heat category will be noted, and the core temperatures of the subjects will be measured at the time of exercise. Prior to exercise, the subjects will be screened to assess 1) their risk of sustaining heat injury, and 2) their aerobic fitness. The subjects will be physicians and the mode of exertion will be their self prescribed training regimens of running on a paved road. After the exercise, the subjects will record their self perceived exertion scale and their self perceived heat category. Phase two is a similar project except that the subjects will be a company of Rangers. The same screening and post exertion self assessments will be made. Core temperatures will be measured by a thermistor passed to a point 15 cm beyond the anal sphincter. WBGT will be measured by meteorological services at Lawson Airfield.

Progress: Study approved locally in late FY 87, no reportable data.

# Detail Summary Sheet

Date: 13 Oct 87      Prot No.: 87-60      Status: Ongoing  
 Title: Care Seeking Behavior After a Mass Casualty Episode

Start Date: Sep 87	Est Comp Date: Dec 87
Principal Investigator(s) Victor G. McGlaughlin, Jr, CPT, MC	Facility: USA MEDDAC, Ft Benning, GA
Dept/Svc: Family Practice Community Medicine	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To determine changes in care seeking behavior in soldiers involved in a mass casualty episode compared with a control group.

Technical Approach: Two questionnaires were administered to 28 soldiers in accident and 130 controls (IBQ & Spielberger State-Trait).

Number of subjects enrolled to date: 158

Progress: Data collection is complete. Statistical analysis is ongoing.

# Detail Summary Sheet

Date: 1 Oct 87      Prot No.: 78-14      Status: Ongoing  
 Title: Intraocular Lens Study.

Start Date: Oct 81	Est Comp Date:
Principal Investigator(s) John A. McCubbin, M.D., MAJ, MC	Facility: USA MEDDAC, Ft Campbell, KY
Dept./Svc: Surgery/Ophthalmology	Associate Investigators:
Key Words:	
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:
	Periodic Review Results

Study Objective: To provide to cataract patients the latest development in ophthalmic surgery concerning the correction of surgical aphakia.

Technical Approach: Extracapsular or extracapsular cataract extraction followed by the implantation of an intraocular lens implant.

Types of lenses being used:

- American Medical Optics, Md1 PC11B Modified C Loop posterior chamber lens.
- IOLAB, Md1 85J, One-piece anterior chamber lens.
- Optical Radiation, Md1 UV40A4 Modified C Loop posterior chamber lens.
- Surgidev Md1 B2024 Modified C Loop posterior lens.
- Storz Md1 MC10 Modified C Loop posterior lens.

Cost per lens: from \$125 to \$375 each.

Subjects enrolled to date: 131

Subjects enrolled for the reporting period: 24

Progress: No significant complications.

# Detail Summary Sheet

Date: 16 Oct 87		Prot No.: 87-28		Status: Completed	
Title: The Effects of Message Framing on Adaption of Healthy Behaviors in Pregnancy.					
Start Date: Mar 87			Est Comp Date:		
Principal Investigator(s) Dr. Diana P. Smith			Facility: MEDDAC, Ft Campbell, KY		
Dept/Svc: Obstetrics/Gynecology			Associate Investigators: MAJ Sylvia Wood, AN MAJ Laurie Davis, AN CPT Nancy Allmon, AN		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To examine the effects of two types of message framing in promoting healthy nutrition and breastfeeding in pregnant and postpartal mothers.

Technical Approach: A sample of 90 pregnant women will be randomly assigned to one of three study groups: one will be assigned to the control group, one to the gain frame message, and one to the loss frame message. At the 20 week visit, the control group will be given routine care, the other groups will be given their assigned messages about breast feeding and eating healthy foods, in addition to receiving routine care. Before reading the messages, baseline demographic data, self efficacy, and health locus of control will be measured. At the 32 week prenatal visit, all subjects will be given the Health Behavior Questionnaire for diet information and feeding method intention and a 24 hour diet history will be obtained. At the 2 week postpartum visit a 24 hour diet history and type of feeding method will be obtained on all subjects.

Number of subjects enrolled to date:

Number of subjects enrolled for reporting period:

Progress: Investigator transferred, unable to obtain report.

# Detail Summary Sheet

Date: 2 Oct 87		Prot No.: 87-39		Status: Completed	
Title: The Relationship of Health Locus of Control, Health Value and Use of Child Restraint Devices.					
Start Date:			Est Comp Date:		
Principal Investigator(s)			Facility:		
Nancy F. Allmon, CPT, AN			USAMEDDAC, Ft Campbell, KY		
Dept/Svc:			Associate Investigators:		
Pediatrics					
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	

Study Objective: To determine if there is a relationship between the use of safety restraint devices for infants and health locus of control and health value of the parents.

Technical Approach: A nonexperimental, correlational design was used to investigate the relationship among maternal health locus of control, parental health value, and usage of restraint devices. There was no manipulation of variables.

Total number of subjects enrolled: 109

Progress: A total of 109 subjects agreed to complete the anonymous questionnaires regarding parent safety practices, maternal health locus of control, and parent health value. Of the 109 subjects who completed the questionnaires, 101 subjects were observed as they left the clinic and rated on their usage of the child safety restraint device. The measurement tool used to assess maternal health locus of control was an adapted form of the Multidimensional Health Locus of Control (MHLC) scale. Internal consistency of the adapted MHLC was found to be .22 for the internal scale, .47 for the chance scale, and .68 for the powerful others scale.

# Detail Summary Sheet

Date: 16 Oct 87		Prot No.: 87-43		Status: Completed	
Title: Accuracy of Skin Temperature Monitoring in Postoperative Patients Using a Liquid Crystal Thermometer					
Start Date: Jun 87			Est Comp Date: Jul 87		
Principal Investigator(s) Carol J. Pierce, CPT, AN			Facility: USA MEDDAC, Ft Campbell, KY		
Dept/Svc: Nursing			Associate Investigators:		
Key Words:					
Accumulative MEDCASE Cost:		Est Accumulative OMA Cost:		Periodic Review Results	
Study Objective: To assess the accuracy of liquid crystal thermometry in comparison to oral temperature measurements in postoperative patients.					

Technical Approach: Prior to surgery when the subject is in the surgical holding area, the E.Z. Temp. Disc will be placed on his/her forehead. Oral temperature will be recorded via the IVAC 811 electronic thermometer by placement of the probe in the posterior sublingual pocket. The oral temperature and skin temperature will be recorded. This will serve as a control. Following surgery, in the Recovery Room, the oral and skin temperatures will be recorded at 15 minute intervals for one hour.

Number of subjects enrolled for reporting period:

Progress: Investigator transferred, unable to obtain report.

# Detail Summary Sheet

Date: 22 Oct 87      Prot No.: 78-14      Status: Ongoing  
 Title: Intraocular Lens Study.

Start Date: Jul 81	Est Comp Date:
Principal Investigator(s) Milne, Henry L, M.D., MAJ, MC	Facility: USA MEDDAC, Ft Jackson, SC
Dept/Svc: Surgery/Ophthalmology	Associate Investigators:
Key Words:	

Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Mar 87 Review Results Continue
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Study Objective: Insertion in selected patients of Tennant Anterior Chamber Anchor Lens.

Technical Approach: Using routine intracapsular cataract techniques, the lens would be inserted prior to final closure of the wound.

Subjects enrolled to date: 599

Subjects enrolled for reporting period: 151

Progress: For this reporting period complications were as follows: 5 vitreous loss; 1 retinal detachment (later reattached); 1 corneal decomposition; 1 postcapsular tear; 2 subluxed post chamber lenses (both were repositioned).

# Detail Summary Sheet

Date: 23 Sep 87      Prot No.: 86-6      Status: Terminated  
 Title: Gender Role Identity, Self Concept and Successful Mothering.

Start Date: Jan 86		Est Comp Date:
Principal Investigator(s) Suzanne H. Brouse, PhD, RN		Facility: USA MEDDAC, Ft Jackson, SC
Dept/Svc: Obstetrics-Gynecology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: To examine the relationship of patterns of feminine characteristics, self concept, perceived success in the mothering role and gender role identity from the second trimester of pregnancy to six weeks postpartum.

Technical Approach: The repeated measures survey design remains unchanged. Potential participants are contacted in a variety of prenatal settings. Subjects complete a packet of questionnaires during early pregnancy, the last trimester and at one month postpartum and six months postpartum. Home interviews at seven months postpartum are completed with those participants willing to do so. Funding for the second year of this three-year project was approved for September 15, 1986 to September 14 1987 by the National Center for Nursing Research, PHS, DHHS. An initial sample of 140 participants has been obtained from all data collection sites since October 1985. Approximately 35 have been obtained from the Fort Jackson, SC prenatal clinic. No significant adverse reactions have been noted related to participation in this study.

Number of subjects enrolled to date: 35

Progress: Investigator transferred, did not submit final report.

# Detail Summary Sheet

Date: 1 Oct 87      Prot No.: 78-14      Status: Ongoing  
 Title: Intraocular Lens Study.

Start Date: Oct 80		Est Comp Date:
Principal Investigator(s) William G. Carey, M.D., MAJ, MC		Facility: USA MEDDAC, Ft Rucker, AL
Dept/Svc: Surgery/Ophthalmology		Associate Investigators: William R. Wilson, MD, MAJ, MC
Key Words: Intraocular Lens      Aphakia Implant                      Surgery Ophthalmology		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: The objective of the ongoing FDA study is to determine the safety of the intraocular lens implant in the human eye.

Technical Approach: In all primary implants during this period, the extracapsular cataract approach was used. A style 20 posterior chamber lens manufactured by Surgidev Corporation was placed in the posterior chamber. In no secondary implants, was the style 10 anterior chamber lens, by Surgidev Corporation, used.\*

Subjects enrolled to date: 414

Subjects enrolled for reporting period: 79 (8 Anterior; 71 Posterior).

Progress: During this period, a small number of secondary intraocular lens implants were accomplished as noted above. However, in contrast to previous years, a different style intraocular lens was used for anterior chamber implantation. This was in keeping with the finding from the FDA that "patients with these types of lenses exhibited long term complications that had not been observed in earlier postoperative exams." Of the eight anterior chamber lens implants performed during this interval, five reflected pure secondary intraocular lens implants in aphakic eyes but three were intraocular lens exchange procedures wherein Surgidev Style 10 anterior chamber lenses were removed and replaced with Cilco SAC-5 anterior chamber lenses. These three patients exhibited various degrees of intracocular lens intolerance which was presumed to be due to the same kind of problems with chronic, low grade, persistent intraocular inflammation that the FDA noted. All of these patients have done very well after the exchange procedure was carried out.

\* During this period, two other types of intraocular lenses were also used during the performance of primary intraocular lens implants for extracapsular cataract procedures. Specifically, Cilco Style SK21U and Vision Care/3M intraocular lenses were used as frequently as the Surgidev Style 20 lens for posterior chamber implantation purposes.

# Detail Summary Sheet

Date: 23 Sep 87      Prot No.: 78-14      Status: Ongoing  
 Title: Intraocular Lens Study.

Start Date: Nov 84		Est Comp Date:
Principal Investigator(s) Mark H. Cook, MD, CPT, MC		Facility: USA MEDDAC, Ft Stewart, GA
Dept/Svc: Surgery/Ophthalmology		Associate Investigators:
Key Words:		
Accumulative MEDCASE Cost:	Est Accumulative OMA Cost:	Periodic Review Results

Study Objective: Provide data to support FDA approval for marketing intraocular devices.

Technical Approach: Surgical insertion of intraocular lens.

Number of subjects enrolled to date: 49

Number of subjects enrolled for reporting period: 27

Progress: There were no serious complications.

AUTHOR INDEX

Algeo JH - 6, 85  
Allanach BC - 4, 60  
Allmon N - 128, 129  
Anderson RC - 89, 94  
Armitage D - 13  
Asp AA - 4  
Aton JK - 48

Baffoni AD Jr - 14, 103  
Barja RH - 1, 2, 7, 21, 22, 86-a, 89, 107  
Barthel HJ - 8  
Baxter CR - 1, 9  
Bellizzi R - 16  
Benton FR - 4  
Berry WJ - 117, 124, 125  
Billingsley J - 8  
Black AS - 106  
Blackwood RA - 83  
Bondra DL - 32  
Boucher RL - 8  
Brand WT - 57  
Bresolin N - 8  
Brewer P - 64, 67  
Brewer TG - 4  
Brigham RA - 6, 7, 13, 14, 91, 99, 105  
Broadnax G - 69  
Brookshire GL - 5, 6, 97, 98, 104, 106, 108  
Brouse SH - 132  
Bruno G - 1, 2, 7  
Buchthal F - 8  
Bunker-Soler AL - 11, 47, 52  
Burke MH - 35  
Busnardo MS - 4  
Bute BG - 14  
Butler JW - 15  
Butterfield HD - 15  
Buxton TB - 1, 9  
Byrne K - 5  
Byrne MP - 6, 93

Caldwell CM - 5  
Carey WG - 133  
Catto B - 1  
Celestino F - 115  
Chadband R - 87  
Charles GA - 7  
Classen JA - 6  
Coles E - 4, 11  
Connelly MA - 115  
Cook JR - 48, 97  
Corbin WR - 16  
Correnti E - 77  
Cowan D - 121  
Cowsar JD - 122  
Cross GM - 3  
Cuff MJA - 37

Dales RL - 6  
Darby PS - 5  
Davies RS - 6, 7, 14, 87, 99, 105  
Davis H - 83  
Davis L - 128  
Demby B - 85  
DiBenedetto M - 25  
Dickens HC - 81  
di Donato-Gonzalez C - 62  
Dieken HA - 63  
DiMauro S - 8  
Donnelly JC - 3  
Donovan LT - 92  
Doyle FM - 16  
Drakeford M - 94  
Drarup C - 8  
Duchin L - 76  
Duffy JC - 9

Eatherly JB - 11  
Ebert FR - 14, 98, 107  
Edwards FH - 6  
Edwards RJ - 11, 46  
Emert RL - 36  
Englekrk P - 4  
Epperly TD - 8, 113, 115  
Ergas RP - 8  
Ernst JL - 1, 7, 22

Faris MR - 4, 11  
Farmer KL - 3  
Ficara A - 21, 31  
Figueroa CY - 79  
Fincher RME - 50  
Fisher JF - 50  
Fogarty JP - 8, 113  
Francis GL - 69, 70, 71, 72  
Frey J - 83  
Frykberg E - 7

Gale TF - 24  
Geniton DJ - 104, 108  
Georgitis W - 4  
Getts A - 69  
Gilman PA - 12  
Ginnett C - 8  
Gleitsmann KY - 5  
Gluckman SL - 7  
Goodell TP - 8, 15, 111  
Gooden SM - 6, 14, 103  
Goodrich AJ - 92  
Gottlieb S - 3  
Gouge SF - 4  
Green JA - 85  
Griffiths GC - 15  
Grogan DW - 84  
Grover PS - 9, 29  
Guill MA - 4, 12, 48, 49, 50, 97  
Gunnell KM - 15  
Guy SC - 38  
Gwinn J - 8

Haburchak DR - 4  
Hamaker RC - 7  
Hamilton JN - 39, 43  
Hancock J - 99  
Handley C - 122  
Hanson BS - 2, 21  
Hartwell GR - 3, 11, 32, 33, 41, 42  
Henderson JM - 116, 117, 123, 124, 125  
Hendricks D - 73  
Herrera J - 4  
Herzwurm PJ - 100  
Hetz SP - 7  
Hill RK - 5  
Hinton A - 9  
Hnarakis EJ - 40  
Hoffman DR - 52  
Hoffman WH - 71

Holt EM - 5  
Hommes F - 5  
Horner JA - 1, 2, 9, 20, 23, 24, 29, 33, 36, 64, 67  
Humes LE - 6  
Hunter SC - 117  
  
Iyengar VG - 4  
  
James J - 8  
James N - 8  
Jennings B - 1, 60  
Jones B - 121  
Jones J - 119  
Jones S - 120  
Jensen PS - 5, 6, 9, 12, 13, 72, 73, 74, 75, 76, 77, 79, 83, 84  
Jewell TW - 4, 5  
John WM - 4  
Johnson A - 13  
Josephson AM - 83  
  
Kern D - 28  
Kidd GS - 4  
Kirby SG - 1, 2, 3, 9, 10, 11  
Koudelka BM - 3  
Krause P - 63  
  
Lamb ES - 4  
LaPiana FG - 7  
Leibach J - 1, 2  
Leone CR - 8  
Leshner JL Jr - 4  
Lett CE - 45  
Levental B - 13  
Levine SH - 15  
Light DE - 44  
Little PB - 11  
Lloyd WC - 8, 15, 110  
Loomis E 83  
Loushine RJ - 42  
Lutcher CL - 12  
  
Mace JE - 124  
Madlon-Kay DJ - 3  
Maniscalco-Theberge ME - 6  
Manning DT - 1  
Marcum JM - 9  
Markowski J - 1  
Martinko TM - 68  
Masuda R - 34

Matthews PS - 11  
 Maury JL - 9  
 Maydonovitch CL - 4, 11  
 McBurney J - 8  
 McCubbin JA - 127  
 McGlaughlin VC - 8, 15, 126  
 McGuire JR - 31  
 McKinnie BJ - 5  
 McNally PR - 4, 11, 59  
 McPherson JC III - 1, 2, 3, 9, 10, 11, 18, 19, 20, 23, 27, 29, 36, 38, 69, 70, 71,  
 McPherson JC Jr - 1, 2, 3, 9, 10, 11, 18, 19, 20  
 McQuade MJ - 2, 3, 28, 29, 31, 36, 37, 38, 40, 43  
 McWhirt E - 105  
 Meyer JB - 8  
 Milne HL - 131  
 Moffitt JE - 52  
 Monihan M - 5, 65, 66  
 Montijo H - 107  
 Moore J Jr - 4  
 Morgenstern M - 7  
 Morrey B - 7  
 Morrison RE - 51  
 Moses KC - 7, 86  
  
 Nang RN - 58  
 Nedderman TA - 33  
 Ness RC - 83  
 Newman J - 61  
 Nguyen TH - 5, 12  
  
 O'Brien DE - 13, 83  
 O'Connor PS - 15  
 O'Hara MA - 15, 110  
 Opelka FG - 7, 13  
 Overly TW - 98  
  
 Palou ME - 3  
 Parker EO - 30  
 Pashley DH - 1, 2  
 Patterson O - 86  
 Paustian PW - 27  
 Penaskovic N - 112  
 Pettine KA - 7, 14, 86-a, 98  
 Pezeshkpour G - 8  
 Pierce CJ - 130  
 Plautz HS - 30  
 Plowman KM - 43, 75  
 Pluss JL - 7  
 Posner DI - 4  
 Prior RW - 1, 2, 3, 9, 10, 23

Quinn MJ - 94  
Quispe G - 7

Raevsky PJ - 44  
Ranlett RD - 5  
Raulin LA - 2  
Rebecca GS - 54, 55, 56  
Reedy M - 83  
Reissman SE - 115  
Reynolds K - 121  
Rhoades RB - 47  
Richards D - 122  
Rissing JP - 9  
Robinson MD - 45  
Rodriguez EJ - 8  
Roesel RA - 5  
Rosen HM - 57  
Rossmann JA - 3, 35, 38, 39, 40  
Rounder JB - 96

Salander JM - 6  
Satava RM - 6, 7, 14, 90, 93, 95, 101, 102,  
Scheidt MJ - 34, 35, 36, 37, 39, 43  
Schenk ED - 5  
Schrieber SK - 78, 80  
Schuller DE - 7  
Scotece GG - 44  
Seitz ML - 82  
Sen JK - 5  
Setser E - 6, 105  
Shaw R - 5  
Sherman RA - 1, 2, 7, 21, 22  
Simpson SL  
Singer MA - 4  
Smith DP - 128  
Smith WA - 46  
Stafford CT - 47, 52  
Stallings RJ - 14, 26, 27, 103  
Stanley WG - 114  
Steely WM - 6, 7, 13, 14, 27, 99  
Sutherland DE - 26, 37

Tamayo F - 76  
Thompson SH - 12, 43  
Tidwell MA - 14  
Tietjen DP - 4  
Tomlinson JP - 15, 121  
Townsend G - 4, 12  
Townsend GG - 5  
Traylor JA - 5, 13  
Tressler CS - 134  
Troxell M - 4, 11

Van Osdel L - 73  
van Halbeek H - 5  
Visvesvara GS - 4  
Volgas DA - 107

Waldron EJ - 4  
Walker L - 89  
Ward DF - 1, 2, 3, 9, 10  
Watson CV - 5, 12  
Weir GT - 5, 12  
Weissler MC - 7  
Wehner MA - 15  
Weller RN - 41, 42  
West SG - 7  
Wien RM - 4  
Wilde GL - 6, 109  
Wilkinson DS - 4  
Wilson WR - 133  
Wolf PL - 83  
Wong RKH - 3, 4  
Wood S - 128  
Woodham JM - 6, 14  
Wymes MR - 5, 13

Xenakis SN - 1, 9, 13, 74, 75, 76, 83

Yancey AL - 1  
Youkey JR - 6

Zegans L - 13

## SUBJECT INDEX

Adolescent females - 69  
Anxiety levels - 62  
Aphakia - 133  
ATLS - 91  
Autotransplantation - 95

Basal cell carcinoma - 48  
Bone graft materials - 29  
Bone lesions - 34  
Bone scanning - 45

Cadmium - 24  
Canal shapes - 42  
Child restraint devices - 129  
Children's depressive symptoms - 74  
Crevicular fluid - 31  
Crutches - 45

Dye leakage - 32

Electron microscopy - 24

Fat embolism - 23  
Fibroblast - 38  
Fibroblasts attachment - 29  
Fibronectin - 38  
Fire ant - 47  
Fire ant allergy - 52, 53

Gastroplasty - 87  
Grant funding - 48, 49

Healing time - 45  
Heparinized blood - 65  
Human fibroblasts - 36  
Hydroxylapatite - 38

Implant - 133  
Implant - 38  
Infrared imaging - 25  
Intraocular lens - 86, 133  
IV catheter - 62

Job performance - 77  
Job satisfaction - 77

LHRH infusion - 69

Metastatic adenocarcinoma - 64  
Military family incest - 79  
Military nursing - 60

Neonatal galactorrhea - 71  
Nicotine - 37  
Nicotine levels - 31  
Nutrition education - 63

Ophthalmology - 133  
Oral cavity - 43

Phantom pain - 22  
Plasma dilution - 65  
Pneumocystis carinii - 43  
Polycystic ovarian syndrome - 69  
Pregnant soldier - 77  
Prolactin levels - 71  
Prothrombin time - 65

Red blood cells - 23  
Root planing - 35  
Root resection - 33

Sodium fluoride - 28  
Spectrometric microanalysis - 67  
Splenectomy - 95  
Stress fractures - 25, 45  
Surfactants - 23  
Surgery - 133

Teratology - 24  
Thromboplastin time - 65  
Titanium - 38  
Tooth hypersensitivity - 28  
Total intravenous anesthesia - 30  
Training injuries - 121

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